UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

November 14, 2002

OFFICE OF
ENVIRONMENTAL INFORMATION

MEMORANDUM

SUBJECT: Peer Review of *Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation* (EPA QA/G-11)

FROM: Nancy W. Wentworth */s/ Nancy W. Wentworth*
Director, Quality Staff (2811R)

TO: Peer Review Panel

Attached is the October 2002, Peer Review Draft of *Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation* (EPA QA/G-11). This technical guidance document was developed by the Environmental Protection Agency to assist those involved in environmental programs needing to design, construct, and operate environmental technology as part of the programs. Environmental technology includes pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

This document is intended to provide clear, coherent, and user-friendly guidance that will serve as a standard tool for managers and officials in the EPA and other state and federal agencies for implementing quality systems when deploying environmental technologies. The purpose of this guidance is to provide users with an understanding of the basic quality assurance (QA) and quality control (QC) procedures, as well as good engineering principles/practices (GEPs) that may be used in planning, implementing, and assessing the design, construction, and operation of environmental technologies. It is intended to complement the requirements defined in the American National Standard *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC E4-1994) by (1) providing basic guidance; (2) outlining applicable planning, construction, and operation elements; and (3) identifying resources and references that may be utilized by environmental professionals during the design, construction, and operation of environmental technologies.

The document contains seven chapters, based on the organization used in the E4 standard. The document is organized as follows after the introduction: Chapter 2 presents general quality system principles and elements, as well as applicable Good Engineering Practices. Chapter 3 describes QA and QC practices for project planning and management, including communication strategies; regulatory permitting and review; resource identification, allocation, and management; the planning and review process; financial planning and cost control; and project staffing. Chapter 4 addresses QA and QC practices related to the design of environmental technologies, including feasibility studies and reviews; resource identification and allocation; organizational and technical interfaces; defining system design practices, the design process, and verification and validation; operation and maintenance (O&M) procedures; and design documentation and approval. Chapter 5 describes QA and QC practices related to construction and fabrication of environmental systems and components. Discussion topics include site selection; contractual arrangements; procurement of supplies, equipment, and services; scheduling and tracking; fabrication inspection, testing, control, and tracking; safety management; and construction certification. Chapter 6 presents QA and QC considerations for the operations and maintenance phase of environmental technology deployment. These include planning and training; O&M considerations during the design, construction, fabrication, system start-up, and normal operations phases; inspection and testing; regulatory and technical compliance; and emergency management and response. Chapter 7 describes quality system procedures for assessment and response as well as verification and acceptance of systems.

You are asked to review all aspects of the document for relevance, usefulness, and overall adequacy as guidance and to provide peer review comments. Your overall review is most appreciated, as well as your comments on the following questions:

1. Does the document begin with a clear indication of what it aims to address and how it would benefit the user?

2. Is it clear this is guidance? The document attempts to avoid being prescriptive, but rather to describe a variety of issues to be addressed depending on the nature of the project and its product's intended use. Is this the right message, and is it communicated effectively?

3. The document discusses both QA and QC concepts and practices and engineering principles and their application. Does it strike the right balance between them in terms of relative emphasis and level of detail?

4. Are the examples helpful in showing how and where QA and QC practices may be used in the engineering design, construction, and operation processes?

5. Overall, how useful will this guidance be for its intended audience?

Please feel free to offer comments and suggestions that go beyond this charge, as you see fit. Use the line numbers provided in the document to reference specific sections with recommended changes. Your suggestions for alternative text will be appreciated.

I appreciate your assistance in this review and need to receive your comments by January 17, 2003. Please send written comments to:

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Attachment

Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation

EPA QA/G-11

Quality Staff
Office of Environmental Information
United States Environmental Protection Agency
Washington, D.C. 20460

PEER REVIEW DRAFT

November 2002

FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed an Agency-wide Quality System, as called for in EPA Order 5360.1 A2 (U.S. EPA, 2000a). The Order requires that all environmental programs performed by or directly for EPA shall be supported by individual quality systems that comply with the American National Standard *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* [American National Standards Institute/American Society for Quality Control (ANSI/ASQC) E4-1994] (ANSI/ASQC, 1994). While previous guidance and requirements documents published by EPA have focused primarily on quality systems for environmental data collection, this *Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation* describes how to develop a quality system for environmental technology programs.

This document provides guidance to EPA employees and other organizations involved in quality system development. It does not impose legally binding requirements on EPA or the public and may not apply to a particular situation based on the circumstances. EPA retains the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. Interested parties are free to raise questions about the recommendations in this document and the appropriateness of using them in a particular situation, and EPA and other parties should consider whether the recommendations in the document are appropriate for the particular situation. EPA may periodically revise this guidance without public notice.

This document is one of the *U.S. Environmental Protection Agency Quality System Series* documents. These documents describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of the Quality System. This document is valid for a period of up to five years from the official date of publication. After five years, this document will be reissued without change, revised, or withdrawn from the *U.S. Environmental Protection Agency Quality System Series* documents. Questions regarding this document or other *Quality System Series* documents should be directed to the Quality Staff at:

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Copies of the *Quality System Series* documents may be obtained from the Quality Staff directly or by downloading them from its Home Page: www.epa.gov/quality.

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CHAPTER 1

INTRODUCTION

1.1 PURPOSE AND OVERVIEW

The purpose of this guidance is to provide users with an understanding of the basic quality assurance (QA) and quality control (QC) procedures, as well as good engineering principles/practices (GEPs) that may be used in planning, implementing, and assessing the design, construction, and operation of environmental technologies. It is intended to complement the requirements defined in the American National Standard *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC E4-1994) (ANSI/ASQC, 1994) by (1) providing basic guidance; (2) outlining applicable planning, construction, and operation elements; and (3) identifying resources and references that may be utilized by environmental professionals during the design, construction, and operation of environmental technologies.

This document is not a "how to" guide or manual. It is a resource for users to help them understand the range and scope of QA and QC practices in support of environmental technologies. There are many other texts and manuals in the literature that can provide more details on the subjects discussed in this guidance.

1.2 BACKGROUND

ANSI/ASQC E4-1994 defines a quality system as ". . . a structured and documented management system describing the policies, objectives, principles, organized authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services." It further explains, ". . . the quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC." The present guidance document presents the basic quality elements for technology implementation. In order to effectively implement these elements, users will find guidance on the basic QA and QC procedures as well as relevant GEPs.

The Environmental Protection Agency (EPA) Quality System conforms to ANSI/ASQC E4-1994. Part C of the E4 standard provides the specifications for the design, construction and fabrication, testing, and operation of environmental technology. The term "environmental technology" includes devices and systems used in environmental programs to duplicate environmental conditions for test purposes, or to control, prevent, treat, or remediate waste in process discharges (e.g., emissions, effluents) or the ambient environment. Usually, this term will apply to hardware-based systems;

however, it can also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants.

QA and QC systems have been developed for a range of disciplines and industries. Within the environmental community, most available guidance on the subject has focused primarily on data quality issues. In more recent years, this topic has been broadened to include the full continuum of environmental projects. For purposes of this document, the quality system includes the development and implementation of comprehensive procedures, as well as process checks to ensure compliance with all aspects of environmental technology deployment. Included in this scope are planning, design, procurement, fabrication, feasibility study, construction, shakedown, operation, maintenance, and performance evaluation of environmental technologies. Project management activities, such as staffing, budget tracking, and organizational communication are also included in this scope. Because quality assurance related to data generation and management is covered by existing EPA Quality System guidance, that topic is not discussed in this document.

1.3 INTENDED AUDIENCE

This document is intended to provide clear, coherent, and user-friendly guidance that will serve as a standard tool for managers and officials in the EPA and other state and federal agencies for implementing quality systems when deploying environmental technologies. The intended audience for this guidance includes QA officers, site remedial project managers, persons responsible for site clean-ups, and other environmental professionals involved with environmental technology design, construction, and operation.

1.4 TERMS AND DEFINITIONS

The following definitions indicate how selected key terms are used in this document. Definitions of additional terms will be found in Appendix A.

Constructor – the party assigned by the developer in charge of technology construction. The constructor's role should be specifically defined in the developer/constructor contract.

Design team – the parties responsible for the design of an environmental technology application. Depending on the scope of the project, this may consist of one or more professionals employed by the developer, or it may include representatives of various contractors and subcontractors as well.

Developer – the organization(s) responsible for site development and technology construction/implementation. The developer may be a single organization, as in the case of a site-specific treatability study for which the technology developer is also the site developer. In other cases, additional parties are involved, especially in the case of a large-scale technology implementation.

Environmental technology – an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Good engineering principles/practices (GEPs) – a broad set of QA, conservation, and safety activities, techniques, and approaches that are commonly accepted throughout the engineering profession.

Owner – the company or organization that has the lead role in the development of the project and implementation of the environmental technology in question. The owner can be a private firm that actually owns the property, or it can be a site developer or architectural and engineering design firm that has been hired by the owner to manage the environmental technology installation from beginning to end, or it may be the private- or public-sector organization responsible for clean-up.

Project team – the parties involved in the construction and/or operation of an environmental technology application. Depending on the scope of the project, this may consist of one or more professionals employed by the developer, or it may include representatives of various contractors and subcontractors as well.

Resident project representative (RPR) – the individual representing the developer for review and approval of project activities.

Responsible party – an individual or organization that has contributed to contamination problems at a site or has assumed site responsibility and is therefore a participant in the environmental technology application.

1.5 PERIOD OF APPLICABILITY

Consistent with the *EPA Quality Manual for Environmental Programs* (U.S. EPA, 2000b), this guidance will be valid for a period of five years from the official date of publication. After five years, this guidance will either be reissued without modification, revised, or removed from the EPA Quality System series.

1.6 ORGANIZATION OF THIS GUIDANCE DOCUMENT

The structure of this document is based on the organization used in the E4 standard. The remainder of the document is organized as follows:

- Chapter 2 presents general quality system principles and elements, as well as applicable GEPs.

- Chapter 3 describes QA and QC practices for project planning and management, including communication strategies; regulatory permitting and review; resource identification, allocation, and management; the planning and review process; financial planning and cost control; and project staffing. This chapter also discusses document and records control.

- Chapter 4 addresses QA and QC practices related to the design of environmental technologies, including feasibility studies and reviews; resource identification and allocation; organizational and technical interfaces; defining system design practices, the design process, and verification and validation; operation and maintenance (O&M) procedures; and design documentation and approval.

- Chapter 5 describes QA and QC practices related to construction and fabrication of environmental systems and components. Discussion topics include site selection; contractual arrangements; procurement of supplies, equipment, and services; scheduling and tracking; fabrication inspection, testing, control, and tracking; safety management; and construction certification.

- Chapter 6 presents QA and QC considerations for the operations and maintenance phase of environmental technology deployment. These include planning and training; O&M considerations during the design, construction, fabrication, system start-up, and normal operations phases; inspection and testing; regulatory and technical compliance; and emergency management and response.

- Chapter 7 describes quality system procedures for assessment and response as well as verification and acceptance of systems.

CHAPTER 2

GENERAL QUALITY SYSTEM PRINCIPLES

2.1 INTRODUCTION

This chapter discusses:
- general guiding principles—quality planning, design of systems, construction of systems and components, operation of systems, assessment and response, and verification and acceptance and
- good engineering principles/practices—design, resource utilization, process operations, process integration, project management, worker training, safety control measures, documentation control, and verification procedures.

This chapter provides an overview of quality assurance principles applicable to process design, construction, and operation. Subsequent chapters will provide QA and QC specifications for specific implementation stages. While these topics can apply to a wide range of operations, they have been tailored to meet the objectives of environmental technology design, construction, and operation.

2.2 GENERAL GUIDING PRINCIPLES

Quality assurance is the system of operations that provides the user with the knowledge and assurance that project activities are likely to meet specific project objectives. In addition, **quality control** activities document the level of quality obtained during process operations. While the general environmental community has been provided with numerous guidance documents that cover specific aspects of quality assurance for environmental data operations, this guidance document breaks new ground by addressing quality assurance and quality control for environmental technology applications.

The following general guiding principles (which are adapted from the E4 standard) underlay the structure and content of this guidance document:

Quality planning – All work involving the design, construction, and operation of environmental technology should be planned, documented, and controlled as needed to achieve conformance with approved criteria.

Design of systems – Processes and procedures should be established and implemented to ensure that environmental technologies are designed using sound engineering/scientific principles and appropriate standards.

Construction of systems and components – Construction, fabrication, manufacture, and erection of systems and components should be performed under appropriately controlled conditions according to the drawings and specifications of the approved design.

Operation of systems – Environmental technologies should be operated in accordance with approved design documentation and operating instructions and guides.

Assessment and response – Work performed during the design, construction, and operation of environmental technology that affects quality should be assessed regularly to ensure that approved planning and design specifications and operating guides are being implemented as prescribed.

Verification and acceptance – The performance of environmental technology should be verified according to its intended use as documented in approved design specifications. When acceptance criteria are not met, deficiencies should be resolved and reassessments conducted as necessary.

Note that these principles span the three main phases of EPA's Quality System: planning (principles 1–2), implementation (principles 3–4), and assessment (principles 5–6).

In addition to these general guiding principles, this document relies on the concept of good engineering principles/practices. GEPs are a broad set of QA, conservation, and safety guidelines that are common to all engineering disciplines. Table 2-1 lists several categories of GEPs that are most likely to be applicable to the design, construction, and operation of environmental technologies. These GEPs will be referred to, as appropriate, in the subsequent chapters of this document.

Table 2-1. Good Engineering Principles/ Practices Applicable to Environmental Technology

DESIGN • Fail-safe/intrinsically safe design of procedures, processes, equipment, structures, and facilities (e.g. alarms, gauges, relief valves, cut-off switches) • Flexible built-in designed procedures, processes, equipment, structures, and facilities • Design of self-correcting procedures and processes
RESOURCE UTILIZATION • Reuse of materials required for technology operations or development • Reduced use of virgin materials, wastes generated, energy sources, and human resources • Recycling/recovery of materials, utilities, and energy sources • Conservation of materials and energy sources • Analysis of availability and interchangeability of all resources, such as materials, personnel,

Table 2-1. Good Engineering Principles/ Practices Applicable to Environmental Technology

and equipment • Substitution of materials and energy sources with cleaner, better, cheaper, more reliable, and more readily available alternatives
PROCESS OPERATIONS • Use of commercially available and tested materials, products, processes, equipment, and supplies • Computerized/remote control of unit operations and processes • Site surveys, including topographical, geological, hydrogeological, hydrological, seismic, wind and weather patterns, as well as social and economic factors
PROCESS INTEGRATION • Automatic communication/notification procedures and processes among all team members involved in technology implementation • Integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and O&M procedures and requirements • Integration/optimization of human, material, energy, and economic resources as well as logistical, political, social, environmental, and technical factors during each critical phase of the project • Modeling and simulation of technical, logistical, economic, social, environmental and political systems prior to, during, and after installation/implementation
PROJECT MANAGEMENT • Sound project management principles/practices—for example, those outlined by the Project Management Institute (PMI) in *A Guide to the Project Management Body of Knowledge* (PMI, 2000)
WORKER TRAINING • Worker training/retraining, including hands-on training during technology construction and operation • Worker registration/certification • Certification/permitting of work procedures, processes, equipment, and environment
SAFETY CONTROL MEASURES • Automatic shutdown of systems, equipment, and processes • Use of automatic safety/corrective action triggers in technical, logistical, political, social, environmental, and economic situations • Use of interlocks as safety measures • Use of lockout/tagout procedures and equipment during systems fabrication/installation and

**Table 2-1. Good Engineering Principles/
Practices Applicable to Environmental Technology**

operations • Prevention of calamities, such as spills, leaks, runaway reactions, and explosions/implosions through process hazard analysis, hazardous operations (HAZOP), failure mode and effects analysis (FMEA), fault tree analysis, and incident investigations
DOCUMENTATION CONTROL • Backup/duplicate copies of documentation • Maintaining/archiving electronic and/or paper copies • Distribution/delivery/circulation list for control documents • Document/records authentication and verification
VERIFICATION PROCEDURES • Document approval procedures • Reviews—peer, project level, program level, organization, and legal • Routine/periodic inspections, testing, and compliance audits of systems, procedures, processes, equipment, etc.

The application of the general QA principles listed above provides a systematic approach to defining and controlling the quality of a project. The following chapters will address each of the principles in turn.

CHAPTER 3

PLANNING AND MANAGEMENT

3.1 PURPOSE AND OVERVIEW

This chapter discusses
- the quality system for the team organization, as it relates to project planning specifications;
- organizational structure, including the chain-of-command and the responsibilities of the project manager, owner, design professional, and constructor;
- project team staffing;
- resource identification, allocation, and management;
- communication strategies and procedures to ensure that the interests of each team member in the outcome of the project are protected;
- permitting and notification requirements to regulatory agencies and for public hearings;
- document and records control; and
- review processes and procedures.

Basic to any technology design and implementation are the planning stages. Planning is an organized activity, typically begun and driven by the manager to define how to design the environmental technology; amass qualified personnel; acquire quality components and materials; and construct, install, and ultimately operate an environmental technology meeting the appropriate quality level. Project management, not only in the planning stages but throughout the project, is equally important for the successful implementation of an environmental technology.

3.2 QUALITY SYSTEM MANAGEMENT

There should be a policy statement that defines quality expectations. These policies are usually defined at the highest level of a company, corporation, or agency and state the level of organizational commitment to quality. In the case of government agencies, this may take the form of an ethics statement or policy that each employee agrees to follow. In the case of private companies, a similar policy may be stated in a corporate handbook or a company credo. In order to ensure that quality performance is achieved, the organization quality policy should state the requirement for employee integrity, confirm management's commitment to meet contractual obligations, and place responsibility for quality with those who perform the work. The quality policy should direct the employees to ascend to the highest possible work ethic, and in turn the organization should provide the resources necessary to achieve these expectations.

While the corporate or organizational policy statement describes the organization's policy at the highest level, that policy should be connected to the type of environmental technology to be tested, maintained, or operated. An identification of the needs and expectations of all involved parties or stakeholders should be included. For example, technology operation or construction usually involves multiple parties. It is important that the identity of these parties, along with their respective roles and responsibilities, be stated and understood. An effective quality system provides an adequate structure and framework of policies, procedures, and activities adequate to satisfy the mission of the organization.

Quality can be defined in terms of meeting the objectives of the manager, design professional, constructor, regulatory agency, and community groups. This definition, therefore, encompasses a wide audience; it reaches out to define quality at several different levels and within different organizations. This definition can include a wide variety of factors, including budget, equipment operation, health and safety, risk sharing, fair treatment, schedules, etc. Therefore, what may appear to be a high quality product on the outside is not necessarily meeting the demands of the project noted above. For example, if a project is completed on time but exceeds the scope of the project budgetary constraints, it may not be judged to be a quality product.

The project-specific quality plan is used to guide personnel in performing appropriate procedures, using specified equipment, and performing specified operational and maintenance checks. These plans should be carefully reviewed and scrutinized prior to project initiation. Subsequent specifications in the plan should be followed by all personnel. Deviations from planned procedures should occur only with permission of the party responsible for technology implementation and should always be documented and approved by QA and technical personnel before being implemented. The purpose of the project-specific quality plan is to ensure all work will be performed by qualified personnel, to ensure that project objectives can be achieved, and to document design, construction, and operational quality. The project-specific quality plan for a technology evaluation, therefore, may reflect an agreement reached among all parties prior to project initiation as to how a process will be evaluated and how it will be determined to be successful or not successful. The importance of this document is that it is a signed statement laying down the ground rules of the evaluation prior to initiation of a project. This helps define project objectives and how to achieve these objectives. It also helps solicit ideas from each participant on how to evaluate a process.

3.3 ORGANIZATIONAL STRUCTURE/CHAIN-OF-COMMAND AND RESPONSIBILITIES

Organizational structure should be defined at several levels. These levels include the project owner or responsible party overseeing the operation as well as subsequent levels, such as individual project or technology operation structure, the organization of individual subcontractors, and the organization of assigned representatives. As used in this document, the term *owner* refers to whatever company or organization has the lead role in the development of the project and implementation of the environmental technology in question. The owner can be a private firm that actually owns the property, or it can be a site developer or architectural and engineering design firm that has been hired by the owner to manage the environmental technology installation from beginning to end, or it may be the private- or public-sector organization responsible for clean-up. Organizational structure elements are defined below.

The first level of organization that should be defined is the project owner's organization. This may be an individual, a private firm, or a government agency. The organizational structure should clearly indicate that project management and QA responsibilities are separate and independent of each other and should clearly define the lines of communication for all parties. Both project management and QA should report to the highest management levels. Responsibilities of each level should be defined and individual responsibilities should be outlined, including those of subcontractors (if any).

Following this level is the organization of the individual project to which the technology operation is to be applied. There may be an overall program or individual projects or both. For defined portions of a project, the owner may be represented by a design firm, legal counsel, and/or other professional support service providers. It is also important that these entities understand and commit to the organizational goals and project objectives.

Programs and/or projects should feature QA organizational independence. Each program and/or project should also provide resources designated for QA organizational leaders and QA assessments. Every quality system should have organizational freedom as well as the freedom and authority to initiate action in order to prevent the occurrence of nonconformities. Therefore, it is important that this authority be clearly defined (and supported by management) for those instances when construction or operation of a technology is stopped and operations reviewed due to unexpected occurrences. In addition, initiation of recommended solutions and verification and monitoring of corrective action should be defined.

In the example of a hazardous waste site remediation project where a responsible party is known, the site developer is typically the organization responsible for site development and technology construction/implementation. The developer may be a single organization, as in the case of a site-specific treatability study where the technology developer is also the site developer. In other cases, additional parties are involved, especially in the case of a large-scale technology implementation. A site developer may subcontract with firms to perform site grading and material handling; installation of infrastructure, such as sewers, foundations, footers, berms, and lagoons; installation of specialized equipment, such as boilers or water treatment facilities; and a variety of other functions. It is important that the site owner convey to the developer and its subcontractors the quality goals and project objectives.

A state or federal oversight agency may be involved in projects including regulatory compliance. For site-specific treatability studies, a third-party evaluator contracted by the site owner or the regulatory agency may be involved. Local community organizations and environmental groups may also be involved in these types of evaluations and in full-scale technology implementations. The needs of all of these organizations, sometimes referred to as "interested parties" should be addressed in the planning stages of the project.

3.4 PROJECT TEAM STAFFING

Different phases of a project call for staffing of appropriate and competent personnel for, at a minimum, the following activities and organizations: site owner/management, design, construction, and operation. The project owner/management may fill a variety of roles depending upon the scope of the project and the experience of the available personnel. These roles may be limited to project oversight by using the design firm as the project manager or may include detailed project management, project design, portions of construction, and process operation. In the first case, design, construction, and operation are likely to involve several organizations employing different personnel for each of the separate stages. Engineering and design professionals are more likely to be involved in everyday activities during design, while some of these same personnel are likely to be in a supervisory or assessment role during construction and operation. Construction personnel may be involved in the design phase to provide input to limitations on the design posed by the site or by construction activities. They may also provide training for system operation.

The owner functions include project management and, potentially, any of the other functions described in this section. Therefore, project managers with sufficient experience in environmental installations are the primary project staff sought by the project owner. This experience would typically include budgeting, scheduling, design reviews, personnel management, and management of various subcontractors. In addition, other support personnel may be needed, including personnel knowledgeable in the legal and regulatory requirements and management controls associated with contracts and management of subcontractors.

The project team involved in the design (e.g., the site owner, the design firm, and the construction contractor) should work together to effectively establish and maintain procedures to complete the definitions of specifications and control and to verify the design of the project to ensure that specifications are met. Typically, the design firm will take the lead in this effort with appropriate oversight from the project owner and input from the construction contractor (if that contractor has already been selected). Engineers develop the specifications and the design plans with input from the project owner, regulators, and other team members of interested parties. Portions of the design may be farmed out to specialty design firms as needed. The project manager for the design firm should appoint someone not directly involved in the design to perform periodic design review, verification, and validation. Ideally, a team of experts should perform design reviews at set intervals. In addition to experienced engineers with expertise in a variety of specialty fields (electrical, mechanical, structural, etc.), the design review team would include experts in such fields as finance, environmental compliance, and safety.

Construction personnel should be competent and experienced in the types of construction to be performed. Construction firms typically have personnel experienced in areas such as materials handling, metal working, welding and pipe fitting, electrical and plumbing installations, concrete work and masonry, and carpentry. In some cases, other areas of expertise may be called for (e.g., heating and ventilation). The construction contractor may use its own personnel, subcontract specialty crafts (e.g., electrical and plumbing) or work requiring specialized equipment (e.g., large cranes), or may utilize day labor (typically for manual labor requiring a minimum of skill). It is the responsibility of the construction manager to ensure that the personnel used are qualified and trained to perform the specific planned construction activities.

Operations personnel should be competent and experienced in operating environmental systems similar to the planned project. These personnel may be current employees of the project owner or may be new hires specifically for the project. Typically, either the design firm or the constructor, or both, will assist the owner in training personnel on the operation of the system. The design firm should provide training on various operational parameters, such as flow rate or throughput.

Training programs should include training of management and field personnel to ensure competency in the required knowledge and skills necessary for technology deployment. Subcontractors who are participating in the program should also be trained, including those added to the program or project at a later date. Personnel training should include types of communication (routine meetings or other correspondence or documentation of changes and problems), the form of communication (this may include meeting minutes, telephone notification, written contract change orders, and progress reports), and the precautions that should be taken (such as methods of handling personnel and sensitive issues or regulatory reporting).

Training should be initiated by the project owner or his/her representative early in the project design phase. Initial training should consist of an overview of the project goals, QA specifications, and overall and project-specific organizational structure and lines of communication. Therefore, development of an effective implementation plan, along with comprehensive training, are critical to project implementation. As the project progresses from design to construction, training programs and procedures are constantly updated to cover construction activities, especially any that were not anticipated in the initial procedures and training. This is often a good time to incorporate “lessons learned” during the design and initial construction stages, especially in regard to communication failures or modifications made to improve communication processes. As the project moves to the technology implementation phase, key training elements include technology operational procedures, field responsibilities, and reporting of field operations. How poorly or how well systems are performing in the field is communicated to all appropriate personnel. Critical to all project phases is determining who is notified and when they are notified. While the transfer of information is important, it is equally important that only appropriate information be forwarded only to the appropriate individuals to avoid “information overload.”

3.5 RESOURCE IDENTIFICATION/ALLOCATION/MANAGEMENT

The management personnel should identify resources available, how they are allocated, and responsibilities of management for resource allocation (this topic is covered in more detail in Chapter 5). During initial planning, it is important to identify resources that are available. Management planning should include identification of specific resources for the project. Resource identification, allocation, and management include both personnel and the funding for personnel, materials, and equipment. The planning procedures should also specify the intended source of these resources. For example, will the supplier or the customer pay for appropriate quality checks, especially if these checks are beyond those normally provided by the supplier? It is the responsibility of project management and, ultimately, of senior management to ensure that resources for quality assurance are available.

The responsibility for project quality control will normally be delegated to individual team members, with oversight by the QA staff. Reviews of employee performance may also be a way of assessing and instilling personal responsibility for ensuring that project quality is maintained. Reviews of individual projects by an independent QA officer is a method for ensuring that organizational policy is followed for specific projects. The organization, however, should provide the resources within its structure to offer the opportunity for review and improvement.

3.6 COMMUNICATION STRATEGY/PROCEDURES

Effective project planning and implementation depend upon good coordination among all parties, which, in turn, depends on effective communication among those parties. The project should be viewed as a whole process from conception to completion, and an overall communication strategy should be developed for the entire project. Critical information should be communicated to the correct team members in a timely fashion. Communication strategies and procedures related to technology operation, construction, and design are similar to other areas of environmental management. These include development and implementation of overall program- and project-specific training procedures and implementation of chain-of-command and lines-of-communication procedures built into the organizational hierarchy.

During the development of a strategy for communication, mechanisms for ensuring that communication is occurring throughout the project team should be implemented. This includes communication with oversight agencies, the developer, the operator, the evaluator, local communities, associated organizations, or others that have a vested interest in the project. Communication can be more effective if team members have already briefed project management or the owner of the technology regarding their expectations and vice versa—hence the importance of agreement among all parties as to how the project will be evaluated, as noted in Section 3.2. The key is to ensure design and/or operation expectations are communicated to all personnel. The goal should be an overall balance that ensures adequate dissemination of information while avoiding over-communication.

3.7 PERMITTING, NOTIFICATION TO REGULATORY AGENCIES, PUBLIC HEARINGS

Since permitting entails regulatory review, time for this review should be built into the schedule. Permits may be issued prior to construction or installation of an environmental technology. Even when permitting is not required, regulatory notification is generally required so that the appropriate agency can make a determination as to the need for a permit. Depending upon the type of project and whether a large construction permit is required, review cycles can be as short as several weeks to more than a year. In addition, time may be required so that public hearings can occur prior to beginning construction. Time should be allowed for public comments and review of the operation at several stages during the project. For example, the regulatory agency may want to review initial (conceptual) plans as a way of determining whether any regulatory requirements are triggered by the proposed project. As the plans are developed, regulatory reviewers may want to review early design drawings (e.g., 30 percent design review) and later drawings, including the final design. Alternatives may be required after review comments have been received. In some cases, a separate operating permit could be required prior to testing or implementation of the process.

Project factors that may need regulatory review and approval (regardless of whether a permit is required) include construction site safety, worker job safety, minority employment requirements, use and disposal of hazardous materials, protection of public health, and air or water emissions during construction or operation. These issues should be addressed very early in the planning stages, and the proper authorities should be contacted to ensure that any applicable regulatory reviews and permit applications are processed in a timely manner. After approval is granted for construction, regulators and other inspectors (e.g., local or county building and health inspectors) may visit the job site to inspect the progress of construction and to independently verify that the design is being implemented as described in the applicable permit. At the end of the project, the regulator may request "as built" drawings and may require testing to demonstrate that the process operates as designed and within the limits of the permit. A permit may be granted based either upon design specification (e.g., a process is designed for a certain maximum throughput) or on the results of a trial run (e.g., the regulator may request that the system be operated at maximum capacity and that emission samples be collected and analyzed to demonstrate compliance with applicable regulations).

3.8 DOCUMENT AND RECORDS CONTROL

For the purpose of this guidance document, the term **document control** is defined as the act of ensuring that program/project-specific documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. Documents that should be controlled are, at a minimum, those that specify requirements, prescribe processes, or establish the design of environmental processes. Examples include drawings, specifications, management plans, procedures, technical reports, and test reports. These documents should be controlled to ensure that the correct documents are being used. Document control should also apply to documents pertaining to legal requirements (e.g., permits, codes).

Applicable GEPs include:
- backup/duplicate copies;
- maintaining/archiving electronic and/or paper copies;
- distribution/delivery/circulation list for control documents;
- document/records authentication and verification;
- document approval procedures; and
- reviews—peer, project level, program level, organizational, and legal.

3.8.1 Document Preparation, Review, Approval, and Issuance

Project management should identify the individuals or organizations responsible for the preparation, review, approval, and issuance of controlled documents. Procedures for controlling documents should be developed. These procedures should specify that the documents requiring control be identified and that the documents then be assigned control numbers (e.g., the document version) and dated. Where applicable, a master list of controlled documents may be specified for a project (e.g., all design drawings and specifications). Regardless of whether a master list is generated, document control numbers should be placed on each page of the document along with the page number, date, and document version. A distribution list for reviewers and/or document users should be incorporated into the document when possible. Document control procedures should be implemented when documents are first prepared.

Documents should be reviewed for adequacy, correctness, and completeness prior to approval and issuance. The organization requesting review should identify the specific review criteria and any pertinent background information. Reviewers should be individuals other than the document originator and should include the applicable technical specialist(s) of each organization affected by the document being reviewed. Other specialists in the fields of QA, environmental compliance, and safety should also review the documents, as needed. The document originator should specify the date that comments are due and, as warranted, the form in which any comments should be transmitted (e.g., document markups, summary memos, or electronic markups or review copies). The document review procedures should also specify the approval process. In some cases, each reviewer may be requested to submit an approval when all comments have been incorporated into the document and the final version is satisfactory to all reviewers. In other cases, the document originator may be responsible for document approval after incorporating review comments.

3.8.2 Document Distribution and Use

The distribution and use of controlled documents and forms that document or prescribe work, including changes and editorial corrections to documents, should be controlled to meet clear specifications. Unless rigorous controls are in place, all controlled documents should be issued to the affected personnel and used at the work location. A limited and known number of copies should be distributed and each document should be clearly marked “Do Not Copy.” This is important to prevent someone not on the distribution list from getting and using a copy that is later superseded but not distributed to that individual. The effective date should be clearly identified on each controlled document; when appropriate, the duration that the document is in effect should be indicated. Naturally, this does not apply in the case of specifications that are in effect for the remainder of the project unless superseded by a new version. Documents should be used only for their intended purpose and any caveats or exclusions should be clearly marked on the document. It is important that appendices, attachments, and footnotes containing such information be included with all copies. As with the distribution and use of controlled documents, the disposition of obsolete documents should be controlled to avoid inadvertent use.

3.8.3 Document Changes

Changes to documents should be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated in accordance with approved procedures. Changes should be clearly noted in the document, and document dates and version numbers should reflect that changes have been made. Procedures for review should normally be the same as those used for the original document. Minor changes, such as grammar, spelling, and minor formatting changes would not normally require review. What changes do and do not require review should be specified in the review procedure.

3.8.4 Document and Record Storage and Archiving Methods/Criteria

Records should be maintained to reflect the achieved level of quality for completed work and/or to fulfill any contract or statutory requirements. Record-keeping procedures should specify what records are to be prepared, reviewed, authenticated, and maintained. Records should be indexed and classified so that they can be expeditiously identified and retrieved. Maintenance procedures for records should include provisions for retention, protection, preservation, traceability, and retrieval. Retention times should be determined based on contractual or statutory requirements or management requirements, whichever is longer. Documents should be stored in such a manner and location as to protect and preserve the information contained in the documents. This means that records are to be protected from damage, loss, and deterioration, whether the records are in paper or electronic form or both. Backups should always be maintained in another location. Document identification and storage procedures should ensure that documents can be traced to their original source and are easily retrievable; this calls for a systematic approach for document storage. When evidentiary records are involved, chain of custody and confidentiality procedures should be prescribed and implemented.

CHAPTER 4

DESIGN OF SYSTEMS

4.1 PLANNING THE DESIGN

> This chapter discusses
> - planning the design with a design team (or design professional) headed by a design team leader,
> - organizational and technical interfaces,
> - design inputs and GEPs to consider,
> - design process,
> - design outputs and GEPs to consider,
> - development of system O&M procedures,
> - review of design and construction/ operational alternatives,
> - design documentation,
> - design verification,
> - design validation and approval, and
> - design changes and GEPs to consider.

The engineering/design professional, contractor, or subcontractor (collectively referred to as the **design team** or **design professional**) should establish and maintain documented procedures to control and verify the design of the "environmental technology" so that the specifications are met. This applies to projects that involve new deployments of "environmental technology" as well as to those that are retrofits or scale-ups of existing ones.

In the design phase of a project, the functional specifications stated during the conceptual phase are given form, and documents are prepared to define the project for construction and operation. Planning and managing the design effort involve elements of organization, staff selection, direction, control, and coordination aimed at achieving quality in the project.

The complexity of the design effort varies with the individual project. For example, a design activity plan may be as simple as an outline of tasks to be performed (for a small, straightforward project) or may be a complex loaded flowchart that includes materials, time, and level of effort requirements.

Prior to initiating any design and/or development activities, specific plans for managing these activities should be prepared. The developer or designee selects a design team, or at a minimum designates an individual who will serve as the **design team leader** for managing the design. Based on the project's technical specifications, the design team leader then organizes/assembles the design team. The design team leader should prepare the **design criteria** that will outline the specifications of the design and define the design process itself. These criteria describe or reference the specific activities and define the design team organization and responsibilities for its implementation. Design criteria should clearly state the design staffing specifications and the selection criteria and provide the basic guidelines for initiation and coordination of the design process and meeting schedules and budgets while maintaining quality. Activities should then be assigned to qualified personnel equipped with adequate resources. These plans are updated as the design evolves.

> Planners and managers should strive to incorporate the following GEPs during design planning:
>
> - fail-safe/intrinsically safe design of procedures, processes, equipment, structures, and facilities;
> - flexible built-in designed procedures, processes, equipment, structures, and facilities;
> - design of self-correcting procedures and processes;
> - analysis of availability and interchangeability of all resources, such as materials, personnel, and equipment;
> - automatic communication/notification procedures and processes among all team members;
> - integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and O&M procedures and requirements;
> - integration/optimization of human, material, energy, and economic resources and logistical, political, social, environmental, and technical factors;
> - modeling and simulation of technical, logistical, economic, social, environmental, and political systems prior to, during, and after installation/implementation;
> - sound project management principles/practices;
> - automatic shutdown of systems, equipment, and processes; and
> - use of automatic safety/corrective action triggers in technical, logistical, political, social, environmental, and economic situations.

In addition, the design criteria typically define/outline the specific technical specifications and project objectives that will form the basis for the designed products. These specifications are communicated to or developed by the project design team. Design criteria may be discussed with regulatory agencies and are modified to meet agencies' requirements when appropriate. Project objectives are part of the work plan developed for a project and distinguish the measurements, details, or information suitable to meet developer specifications. It is not enough to state the objective; there should also be a description of the methods that will be used to determine whether or not the objectives are met. These elements also describe methods or procedures that will yield information to determine acceptable quality and quantity to support project decisions. Defining these objectives will determine the ultimate ability of measuring project success. The user should therefore keep in mind the ultimate goal of their operation when defining project objectives. For example, is the operation a long-term technology for clean-up of a particular contaminant or site, or is it for demonstration purposes? Is this technology to be used at other, similar sites also under the purview of the site responsible party? Will design and construction phases be time limited in order to meet operation specifications? Who will operate and maintain the technology? Who is ultimately responsible for ensuring that technology specifications have been achieved and, if the technology is for clean-up efforts, who will be responsible for certifying site clean-up? These questions help to provide the foundation and designate the parties who can define specific project objectives.

Design criteria include the various GEPs that will drive the design processes. Designed procedures, equipment, structures, and facilities should be flexible to the extent possible to handle variations and most plausible system input situations. When toxic or highly dangerous materials are involved, designs should include sufficient safeguards to be fail safe or intrinsically safe. Interchangeability of resources, such as materials, personnel, equipment, etc. should be considered during the design planning phase as a means to control project cost and improve system reliability and resilience. During the design planning stage, the purchasing and procurement, fabrication and construction, and the operations and maintenance teams should be consulted to avoid compromising financial, logistical, or technical situations, after the fact.

Construction and deployment of an environmental technology entails that specific operations be followed and maintained; however, because many environmental technologies may be innovative and may have undergone very little field testing, the design team is responsible for achieving quality objectives during construction based upon previously set standards and performance criteria and based upon their experience and ability to adjust designs to adapt to new applications and to changing conditions. The selection of the design team leader and design professional may be a key aspect in maintaining quality control during construction.

When the project involves retrofitting or scale-up of an existing environmental technology, the design team should review and analyze all available documentation related to the planning and implementation of the original design, construction, and system operations, and if possible, interview and consult with the previous design team staff. Incident reports and documentation should be carefully reviewed and analyzed to avoid potential pitfalls.

4.1.1 Feasibility Studies and Reviews (FSRs)

In some cases, conceptualizing and planning for construction and deployment of environmental technologies may entail the development and study of various alternatives. This may be particularly true when design decisions involve different choices of technology or engineering approaches. These are often known as **feasibility studies**. Such activities are a joint effort of the owner, design professional and, if available, the constructor and operator. The resources spent in formulating, investigating, and studying alternative approaches to decisions will vary depending on the size and complexity of the project.

Prior to undertaking the formal design and development activities, the design team may conduct feasibility studies and reviews to gain full understanding and establish a sound working knowledge of the various technical, logistical, and economic factors; challenges; and issues involved with the deployment of the specific environmental technology at the specific site. Controls and measures should be defined, identified, and set in place to allow updating of the various FSRs during the course of design, construction, and operation of the deployed technology.

Technical feasibility studies include life cycle analysis, environmental impact statements, and investigation of alternative solutions. The various alternatives studied will affect project performance and appearance, life-cycle cost, cost/benefit ratio, schedule of completion, and socioeconomic and environmental impacts. The number of alternatives chosen for examination, the extent to which each is subjected to detailed planning evaluation, and whether more than one "preferred" alternative is selected for final design are key decisions best made early in the project planning and scoping process. Key aspects for consideration are listed below:

> In addition to the GEPs listed in Section 4.1, designers should consider the following GEPs when conducting the various FSRs:
>
> - reuse of materials required for technology operation or development;
> - reduced use of virgin materials, wastes generated, energy sources, and human resources;
> - recycling/recovery of materials, utilities, and energy sources;
> - conservation of materials and energy sources;
> - substitution of materials and energy sources with cleaner, better, cheaper, more reliable, and more readily available alternatives; and
> - use of interlocks as safety measures.

- Be responsive to the project specifications.
- Recognize legal requirements.
- Address any preestablished criteria agreed upon by the affected parties.
- Comply with land use and zoning regulations.
- Be functionally efficient, i.e., technically correct, cost-effective, and constructable; safe; and environmentally and aesthetically acceptable.

Logistical feasibility studies include analyses of alternatives for the procurement, distribution, deployment, maintenance, and replacement of materials and personnel. Alternatives that may be considered include the following:

- Scheduling alternatives, such as a schedule selected by the contractor, owner, or both; rapid (compressed) schedule at extra cost but desirable because of short construction season or compensating advantage such as more rapid return on investment (for example, return of a remediated site for productive commercial use); delayed versus immediate construction start; seasonal construction; and a schedule imposed by a third party, such as a regulatory agency.

- Functional alternatives, such as materials handling methods; traffic flow arrangements (patterns in air, water, land, people, or products); types of travel modes (vehicle type, size, style); methods to provide fish passage at barriers in waterways; space allocations, clear-span requirements in buildings; and public, private, or joint-use options for a facility.

- Conceptual planning or layout alternatives, such as alternative route studies, site locations, drainage methods, structural systems and materials, and construction methods affecting design.

Economic feasibility studies include cost-benefit analyses and analyses of short- and long-term economic impacts on the community and the region. Cost alternatives that should be carefully analyzed and considered include design cost, capital cost of construction, operation and maintenance costs, various life-expectancy or design-life periods, return on investment, cost comparison of deploying the environmental technology on a full-scale now basis versus deploying it in stages, value of extra cost for aesthetics, and cost/benefit ratios.

Feasibility studies allow for insight and investigation into all aspects that may impact technology construction and operation. The FSRs stated previously are all important in considering alternative solutions and whether those alternatives can offer a realistic solution.

4.1.2 Resource Identification and Allocation

A project for the design team could involve more than one design professional discipline. The goal of each design team, be it single or multidisciplinary, is to meet the project's specifications. Team members from each design discipline are expected to integrate their technical knowledge with that of the practitioners from other disciplines to satisfy the overall design objectives. Identification and allocation of the correct mix of design team professionals is therefore crucial to achieving the project's technical as well as economic success.

Identification and allocation of resources should be conducted during design planning in order to ensure adequate resources will be available during construction and operation of a technology. Resource requirements should specify the level of quality needed to accomplish the stated objectives. Personnel, for example, should be trained in QA principles and in all standard operating procedures governing their areas of responsibility. Each professional discipline plays a role in offering input into the technology construction. These include engineers, scientists, and perhaps geologists or others familiar with the workings of the process and of the site being considered for remediation. The design planning phase should identify how that team will be coordinated and should define the roles of the owner, the oversight agency, the site responsible party, etc.

4.2 ORGANIZATIONAL AND TECHNICAL INTERFACES

Organizational and technical interfaces should be identified during planning and controlled during the design efforts and should be coordinated among the participating organizations and individuals, such as the site owner, regulatory agencies, design professional, construction/fabrication contractor, equipment and materials supplier, and the technology operator. A typical design team will consist of scientists and engineers from various disciplines, for example, chemistry (soil, water, air, as well as analytical), physics, life sciences, microbiology, physical sciences, geology, hydrogeology and chemical, mechanical, civil and environmental engineering.

When the project involves retrofitting or scale-up of an existing environmental technology, to the extent possible, interfaces with the previous designers, construction contractors, and suppliers should be identified and incorporated into the prevailing organizational structure. Overall project and technical organizational flowcharts should be used to identify the participating organizations and individuals and their respective roles, responsibilities, and authority.

Interface controls should include the assignment of responsibility and establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. Design information transmitted across interfaces should be documented and controlled, for example, through distribution and sign-off sheets. Prior to design initiation, the methods, modes, and standards for information transfer, documentation, and control should be established and made known to all participants. Transmittals should identify the status of the design information or document provided and, when necessary, identify incomplete items that call for further evaluation, review, or approval. When it is necessary to initially transmit design information orally or by other informal means, the transmittal should be confirmed promptly by a controlled document. Likewise, electronic transmittals should also be promptly confirmed via electronic means or by other acceptable controlled documents.

Typically, the design team leader keeps the developer and design team members informed on the design's status, normally submitting monthly (or more frequently, if necessary) progress reports to the owner. These reports contain information on meetings held and work accomplished in the subject period. Most importantly, design problems and issues should be recognized as early in the process as possible and reported to the appropriate decision makers (e.g. technology developer); those that may prompt a change in scope, budget, or schedule should be promptly identified, documented, communicated, and resolved among the participating parties.

4.3 DESIGN INPUTS

Design input specifications relating to the product components and processes of the intended environmental technology, including applicable technical, logistical, economical, social, statutory, and regulatory requirements, should be identified and documented.

Prior to the start of the design phase, the owner and his/her design, construction, and operations teams, separately as well as collectively, should identify all project pertinent design characteristics that are critical in terms of safety and health. Applicable **design inputs**, such as design bases, conceptual design reports, performance specifications, regulatory requirements, codes, and standards should be documented and controlled by those responsible for the design in accordance with the following specifications:

- Design inputs should be identified and documented and their selection reviewed and approved by those responsible for the design.

- Design inputs should be specified and approved on a timely basis and to the level of detail appropriate to permit the design work to be carried out correctly in a manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.

- Changes from approved design inputs and reasons for the changes should be identified, approved, documented, and controlled.

- Design inputs based on assumptions that call for reverification should be identified and controlled.

Some design inputs may reflect consideration of environmental and ecological issues identified by other interested parties.

During the design input phase, as part of the technical directives, the developer usually outlines the various desired GEPs that the design professional incorporates into the design, to the extent possible. Design input should include the specification that the designed output/product, when practicable, utilize commercially or readily available or off-the-shelf products. Use of these commercially available or off-the-shelf products (i.e., commercial-grade items) should not exempt the designed output/product from the specifications of design review, verification, validation, documentation, and certification. Other GEPs that should be considered during design input are noted in the box to the right.

Codes and standards are developed by governmental units and industry or professional-technical associations to protect the public's health and safety. Early identification of appropriate codes and standards can prevent reworking plans and specifications and save considerable cost and delay. Since codes and standards typically address particular aspects of design, construction, and operation of a technology, the design team can expect to find a number of codes and standards applicable to a project, including those pertaining to civil, mechanical, electrical, structural, and process engineering, as well as architecture. Depending upon the complexity of the project, there may be many applicable codes. Applying codes and standards to design may sometimes be difficult, especially for design professionals working on a project in an unfamiliar geographical area, as in the case of a remote but hazardous or toxic waste site. Local and regional codes are common and are usually modified versions of national model codes; therefore, design based solely on national model codes may not always satisfy the requirements of a local authority.

The following GEPs should be considered when establishing/developing the design inputs:

- reuse of materials required for technology operation or development;
- reduced use of virgin materials, wastes generated, energy sources, and human resources;
- recycling/recovery of materials, utilities, and energy sources;
- conservation of materials and energy sources;
- substitution of materials and energy sources with cleaner, better, cheaper, more reliable, and more readily available alternatives;
- use of commercially available and tested materials, products, processes, equipment, and supplies;
- computerized/remote control of unit operations and processes;
- use of lockout/tagout procedures and equipment during systems fabrication/installation and operations; and
- prevention of calamities through process hazard analysis, HAZOP, FMEA, fault tree analyses, and incident.

4.4 DESIGN PROCESS

The responsible design organization(s) should define, manage, and document the design activities on a timely basis and to the level of detail appropriate to permit the design process to be carried out in a correct manner and to permit verification that the design meets the specifications. Design documents should be adequate to support facility/system design, construction, and operation. They should be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can understand the documents and verify their adequacy without recourse to the originator. Appropriate and applicable technical and quality standards also should be identified and documented and their selection reviewed and approved.

Changes from all specifications and standards, including the reasons for the changes, should be identified, approved, documented, and controlled. Design methods, materials, parts, equipment, and processes that are key to the function of the structure, system, or component should be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, should be made available to cognizant design personnel. The final design (approved design output documents and approved changes thereto) should:

- be related to the design input by documentation in sufficient detail to permit design verification;
- contain drawings, specifications, and other design output documents as well as appropriate inspection and testing acceptance criteria; and
- identify assemblies and/or components that are part of the item being designed. (When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection and/or testing to specifications that are more restrictive than the supplier's published product description, the component part should be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.)

If the design effort is to support an existing technology retrofit or scale-up, the designers should take into account the design inputs, design outputs, and the actual performance of the existing products and processes against their respective design expectations. Such analyses provide a better understanding of the limitations of the technology and the challenges it is likely to face when retrofitted and/or scaled up.

Documenting design for technology operation or construction provides the means to ensure appropriate procedures are followed. In terms of documentation, peer and QA review should be incorporated to ensure it will be understandable and meet specifications. Maintaining and ensuring quality during the design process entails that specific documentation standards be followed so that appropriate and relevant information is conveyed to all personnel involved during the design, construction, and operation phases of the environmental technology.

4.5 DESIGN OUTPUTS

Design output should be documented and expressed in terms that can be verified against design criteria (including specific acceptance criteria) and validated.

Design output should:

- meet the design-input specifications,
- contain or make reference to acceptance criteria, and

- identify those characteristics of the design that are crucial to the safe and proper functioning of the technology and its components (e.g., operating, storage, handling, maintenance, and disposal requirements).

Design output documents are usually reviewed and approved before release. The distribution of the design output documents should be controlled and, where deemed critical, verified.

> The following GEPs should be considered when developing/generating the design outputs:
>
> - reuse of materials required for technology operation or development;
> - reduced use of virgin materials, wastes generated, energy sources, and human resources;
> - recycling/recovery of materials, utilities, and energy sources;
> - conservation of materials and energy sources;
> - substitution of materials and energy sources with cleaner, better, cheaper, more reliable, and more readily available alternatives;
> - use of commercially available and tested materials, products, processes, equipment, and supplies;
> - use of interlocks as safety measures;
> - computerized/remote control of unit operations and processes;
> - use of lockout/tagout procedures and equipment during systems fabrication/installation and operations; and
> - prevention of calamities through process hazard analysis, HAZOP, FMEA, fault tree analysis, and incident investigations.

4.6 DEVELOPMENT OF SYSTEM OPERATING AND MAINTENANCE PROCEDURES

The operational characteristics and maintenance specifications of the project after completion and subsequent start-up determines the success in meeting project goals. O&M factors influence life-cycle costs, continuity of service, durability, public health and safety, environmental impact, and other features of the completed environmental facility/program/project. O&M specifications should be considered in each phase of project planning, design, construction, and start-up.

In the preliminary design phase, decisions are made relating to site selection and access, process choice, equipment selection, and other elements that impact operation and maintenance of the completed project. Since decisions made here limit flexibility in subsequent phases of the project, O&M coordinators and advisers should be consulted for choices of brands or models of equipment to be selected, arrangements or layout of facilities, access for equipment repair, routine operation and maintenance procedures, and other design features that influence O&M costs and activities.

Effective operation and maintenance entails quality products and services that perform according to project specifications. The various stages of the project (planning, design, construction, start-up, and operation) each involve input from O&M staff. Roles of O&M staff are certainly weighted towards process operation, but if input is not provided during planning or design, technology processes may suffer from over-design whereby standard "off the shelf" equipment is not used or they may also suffer from operations that are difficult to maintain. O&M staff input provides a "reality check" for the design and planning stages and provides assistance during construction and start-up.

Environmental technology should be operated in accordance with approved design documentation and operating instructions and guides. Designers should ensure that the technology operating guides and manuals include, but are not limited to:

- appropriate controls for materials (including consumables) and measuring and testing equipment;
- configuration management;
- operating procedures and parameters for specific components and systems configuration, including specified safety limits;
- spill, fire, and other hazard safety procedures;
- process equipment control and maintenance, including specifications during abnormal conditions for inspection and test situation and fault and emergency conditions;
- special environments, time, temperature, or other factors affecting the quality of operation; and
- the skill, capability, and knowledge of operators to meet operational, environmental, and quality goals. This should be accomplished through the use of specific standards, resources, and worker training and certification.

4.7 REVIEW OF DESIGN AND CONSTRUCTION/OPERATIONAL ALTERNATIVES

At appropriate stages of design, formal documented reviews of the design are planned and conducted. Participants at each design review should include representatives of all pertinent functions/disciplines concerned with the design stage being reviewed, as well as other specialist personnel, as required. Records of all such reviews should also be maintained.

Design reviews or audits for purposes of validation are cornerstones of the design professional's QA program. They, however, do not replace the ongoing checking process of the design team to identify and correct discrepancies in design details. Design review is an internal QC procedure usually carried out by members of the design team and a review board selected for their expertise. Design audits are performed by individuals other than members of the design team. Design reviews or audits have the purpose of establishing the levels of quality of the design by identifying unsound concepts, analyzing the overall feasibility of the project, eliminating redundancies and "re-invention of the wheel," and assisting in interdisciplinary coordination.

4.8 DESIGN DOCUMENTATION

The design professional should establish and maintain documented procedures for identification, collection, indexing, access, filling, storage, maintenance, and disposition of design documents including drawings, calculations, and results, as well as references, standards, codes, design basis (including GEPs), and assumptions used in the design process. Under almost all circumstances, design results and outputs are checked, verified, and certified by a licensed professional belonging to the pertinent discipline. When the project involves technology retrofit or scale-up, the designer should recheck, reverify and, if determined to be critical for the current design, even recertify the design results and outputs of the preceding version of the technology.

Design documentation and records, which provide evidence that the design and the design verification processes were performed in accordance with project specifications, should be collected, stored, and maintained in accordance with documented procedures. The documentation includes not only final design documents (such as drawings and specifications) and revisions thereto, but also documentation that identifies the important steps, including sources of design inputs that support the final design.

4.9 DESIGN VERIFICATION

As with data verification, design verification ensures that calculations have been checked, and designs have been compared with previous proven designs. The verification process evaluates the completeness, correctness, and conformance or compliance of the design in terms of meeting contractual, method, or procedural specifications.

At appropriate stages of design, design verification should be performed to ensure that the design stage output meets the design stage input specifications. The design verification measures should be recorded. The following measures can be applied to verify the adequacy of the design:

(a) Design verification should be performed using one or a combination of the following methods:

- performing alternative calculations (calculations or analyses that are made using alternate methods to verify correctness of the original calculations or analyses and the appropriateness of any assumptions, input data used, any computer programs, or other calculation methods used);

- comparing with prevailing/proven design (for example, when the project involves retrofitting or scale-up of existing technology);

- testing under laboratory, field, or simulated conditions (for example, treatability tests and/or mathematical modeling coupled with computer simulation); and

- reviewing the design stage documents before release.

(b) The particular design verification method should be identified and its use justified.

(c) The results of design verification should be documented, including the identification of the verifier.

(d) Design verification should be performed by competent individuals or groups other than those who performed the original design (but they may be from the same organization). If necessary, this design verification may be performed by the originator's supervisor providing that:

- the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design,

- the supervisor is the only individual in the organization competent to perform the verification, and

- the determination to use the supervisor is documented and approved in advance.

(e) Design verification should be performed at appropriate times during the design process.

- Verification should be performed before release for procurement, manufacture, construction, or release to another organization for use in other design work.

- Design verification should be completed before relying on the item to perform its function.

(f) The extent of the design verification should be based on the complexity of design, risk, uniqueness of the design, degree of standardization, technology's state of the art, and similarity with previously proven designs. When the design has been subjected to a verification process in accordance with this standard, the verification process need not be duplicated for identical designs.

(g) Use of a previously proven design should be controlled as follows:

- The applicability of standardized or previously proven designs should be verified with respect to meeting pertinent design inputs for each application.

- Known problems affecting standard or previously proven designs and their effects on other features should be considered.

- The original design and associated verification measures should be adequately documented and referenced in the files of subsequent application of the design.

- Changes in previously verified designs prompt reverification. Such reverifications should include the evaluation of the effects of those changes on the overall previously verified design and on any design analyses upon which the design is based.

(h) Design verification and approval should be performed in a timely manner.

4.10 DESIGN VALIDATION AND APPROVAL

Design validation is performed through assessments to ensure that the designed products, processes, and procedures conform to defined user needs. It is confirmation by examination of objective evidence that the particular specifications for a specific intended use are fulfilled. Typically, design validation follows successful design verification and prior to installation and/or final deployment.

Validation is normally performed under defined operating conditions and on the final product, but may be appropriate in earlier stages prior to product completion. Validation activities are used to demonstrate that the designed product is an acceptable representation of the process or the system for which it is intended, and that the product performs within defined limits for each applicable parameter.

Validation methods, test data (including any software-generated results), and conclusions should be documented in a form that can be understood by an independent individual technically competent to understand the particular item or product under study. The documentation is then reviewed to assess the adequacy and correctness of the documentation in meeting the validation test specifications.

When design adequacy is to be validated by qualification tests or pre-operational test runs, the tests are identified and the test configuration are clearly defined and documented. Testing demonstrates adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item should perform satisfactorily should be considered in determining the most adverse conditions. When the test is intended to verify only specific design features, the other features of the design are usually verified and validated by other means. Test results should be documented and evaluated by the responsible design organization to ensure that test specifications have been met. Test results should then be reviewed and validated by an independent individual technically competent to understand the particular item or product under study.

If validation testing indicates that modifications to the item are called for to obtain acceptable performance, the modification should be documented and the item modified and retested or otherwise validated to ensure satisfactory performance. When tests are performed on models or mockups, applicable scaling laws are normally identified or established and verified. The results of model test work are then subjected to error analysis, when applicable, prior to use in final design work.

Applicable GEPs include those that were identified in the Design Input and Design Output sections.

4.11 DESIGN CHANGES

All design changes and modifications should be identified, documented, reviewed, and approved by authorized personnel before their implementation using clearly defined documented procedures. Design changes should be controlled in accordance with the following specifications:

(a) Changes to final designs, field changes, and nonconforming items dispositioned "use as is" or "repair" should be justified and subject to design control measures commensurate with those applied to the original design.

(b) Design control measures for changes should include provisions to ensure that the design analyses for the item are still valid.

(c) Changes should be approved by the same groups or organizations that reviewed and approved the original design documents.

- If an organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization should be designated.

- The cognizant design organization should have demonstrated competence in the specific design area of interest and have an adequate understanding of the intent of the original design.

(d) If a significant design change becomes necessary because of an incorrect original design, the design process and design verification methods and implementing procedures should be reviewed and modified as appropriate. These design deficiencies should also be documented.

(e) Field changes should be incorporated into the applicable design documents.

(f) Design changes that affect related implementing procedures or training programs should be communicated to the appropriate organizations.

> Designers should consider the following GEPs when addressing design changes:
> - worker training/retraining, including hands-on training;
> - worker registration/certification;
> - certification/permitting of work procedures, processes, equipment, and environment; and
> - routine/periodic inspections, testing and compliance audits of systems, procedures, processes, equipment, etc.

CHAPTER 5

CONSTRUCTION/FABRICATION/INSTALLATION OF SYSTEMS AND COMPONENTS

5.1 INTRODUCTION

The QC components of construction quality control discussed in this chapter are:

- site selection and development;
- review of resources;
- construction contracts;
- contractual arrangements;
- procurement;
- scheduling and tracking;
- cost management;
- materials management;
- labor/workforce management;
- safety management;
- inspection, testing, control, and tracking; and
- completion certification and approval.

Quality in the construction, fabrication, and installation phase of a project is achieved by establishing, implementing, and maintaining documented procedures to control and verify the quality of construction activities to ensure that technical specifications and QA and QC specifications are met.

Project planning for the construction, fabrication, and installation of an environmental technology should be undertaken by the developer or the lead agency. It is important to note that planning for construction takes place during all project phases prior to award of the construction project. Planning for construction involves an evaluation of the QC components listed in the text box above. The results of these evaluations should help define the contracting strategy and guide the project team in determining the field organization of project facilities.

In managing construction activities, the developer or team leader may plan and implement construction activities in simple projects. More frequently, the technology developer will contract with a design professional or the constructor to perform the design and planning activities. Once design and planning activities are completed, the developer will then contract with a construction professional to fabricate the environmental technology. Alternately, as part of his/her contract, the design professional may also prepare contractual documents for the developer or actually contract with the constructor. In both cases, the design professional will be in charge of preparing design drawings and specifications, establishing schedules, and performing oversight of the constructor. The constructor, in turn, is responsible for specific compliance with the specifications for the project, including planning and enforcement of site safety programs (designated in a separate health and safety plan); means, methods, and sequencing of construction; management and payment of subcontractors and suppliers; meeting applicable codes, permit requirements, and other public agency regulations pertaining to his/her operations; and quality control related to construction activities as specified by the developer and as discussed in this section.

For many of these activities, the constructor looks to the resident project representative (RPR), who is representing the developer, for review and approval of his/her activities under the terms of the contract. The responsible party usually contracts with the design professional to provide these technical services and may also authorize the design professional to perform certain administrative duties, including authorization to act as the owner's RPR for field construction activities.

5.2 SITE SELECTION AND DEVELOPMENT

Site selection and development activities may take place during the planning and design phases. However, prior to commencement of these activities, the project site specifications should be established and documented. It is assumed, for example, that site selection has been previously determined and documented and that levels of contamination are appropriate for the specific environmental technology being constructed. Other aspects of site development typically include, but are not limited to, construction of access roads and rails; extension of utilities to the site; construction of independent utilities, if required; construction of lay-down areas and fabrication yards; traffic control measures including detour routes; and relocation of utilities, highways, rail, and other facilities. Utilities can include site logistical operational requirements as well as requirements of the technology.

Road and utility contracts may be part of the overall construction contract or may be issued separately from and prior to the construction project. In the latter case, care should be taken to coordinate with the design contractor to ensure that all aspects of construction are anticipated so that road and utility work is adequate to support site construction. Utility extensions and relocations are frequently performed by the applicable utility, although such activities may be included in the overall project construction contract. Considerations of cost, construction sequencing and scheduling, site congestion, safety, and contractor qualifications will impact the decision on the contractual approach.

GEPs that are applicable to site selection and development include:

- analysis of availability and interchangeability of resources, such as materials, personnel, and equipment;
- site surveys, including topographical, geological, hydrogeological, hydrological, seismic, wind and weather patterns, as well as social and economical factors;
- automatic communication/notification procedures and processes among all team members;
- integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and O&M procedures and requirements;
- modeling and simulation of technical, logistical, economic, social, environmental, and political systems prior to, during, and after installation/implementation;
- use of lockout/tagout procedures and equipment during systems fabrication/installation and operations; and
- prevention of calamities through process hazard analysis, HAZOP, FMEA, fault tree analysis, and incident investigation.

5.3 REVIEW OF RESOURCES

Resources available to the responsible party, design professional, and constructor for project construction may place constraints on project activities and influence the decisions pertaining to project specifications, planning and design, contracting strategies, and construction operation and quality. It is therefore crucial for the responsible party and project team to identify all the resources (financial, personnel/human resources, and construction materials/processes/capabilities) deemed appropriate for the technology deployment and to critically examine the type and extent of resources available.

Reporting procedures and delineation of responsibilities for resource reviews should be established. In addition, such reviews should result in the establishment of procedures and mechanisms for securing the needed resources for construction within the framework of prevailing local, state, and federal regulations.

5.3.1 Financial Resources

> Applicable GEPs for financial resources include:
> - design of self-correcting procedures and processes, and
> - integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and O&M procedures and requirements.

The technology developer or responsible party is in charge of securing funds to plan, design, and construct the project. This may be a cooperative effort between several different parties and/or agencies. The availability of these funds, beginning with the onset of the planning phase, will be critical to completion of the project in a timely fashion and to the ultimate quality of the project. Adequate funding of "up front" activities, such as preliminary planning, hydrogeological studies, alternative investigations, and other activities to delineate design criteria and project specifications is crucial to adequately define the design and reduce the risk of unanticipated events during construction. This can include, for example, additional funding for verification of contaminant levels at the site in order to ensure operational success of the technology.

The completion of a project in a manner that ensures the quality of the constructed system entails that the financial interests of all members of the project team (responsible party, design professional, constructor, suppliers, subcontractors, specialty fabricators, and other advisors, such as legal and business professionals) be considered. The financial capabilities should be considered in the planning stages as well as in the contractual and implementation phases of the project.

5.3.2 Human Resources

During the initial stages of project planning, the responsible party evaluates the human resource needs of the project. Continuity of key management and professional staff and the availability of a skilled workforce are important factors that contribute to the quality of the project. Continuity of the design professional through all project phases aids in communication and ensures that interpretation of plans is consistent with their original intent, minimizing unnecessary and detrimental construction change orders. Project team staffing was discussed in detail in Section 3.4.

GEPs that apply to the management of human resources include:

- analysis of availability and interchangeability of all resources, such as materials, personnel, and equipment;
- integration/optimization of human, material, energy, and economic resources and logistical, political, social, environmental, and technical factors during each critical phase of the project;
- worker training/retraining, including hands-on training; and
- worker registration/certification.

As part of the site construction, project continuity and quality can be improved by evaluating workforce capabilities to identify the competence of the workforce and any training needs. Discussions with local construction firms and building contractors, labor unions, and vocational training institutions can assist in determining the availability of a skilled workforce. In cases where the constructor faces workforce shortages, project quality can be safeguarded by adding construction supervisors, implementing additional quality control measures, initiating worker training programs, and modifying designs to accommodate modular components that are fabricated and assembled at the factory prior to transport.

5.3.3 Construction Materials

The availability and cost of materials for construction influence planning, design, and construction operations. In planning construction activities, the responsible party or authorized representative should evaluate the availability and cost of specific materials in the local market, transportation costs for materials not available locally, storage and preparation procedures, scheduling aspects related to transportation and specially prepared materials, and legislative or contractual requirements to

Applicable GEPs for construction materials include:

- reuse of materials required for technology operation or development
- reduced use of virgin materials, wastes generated, energy sources, and human resources;
- recycling/recovery of materials, utilities, and energy sources;
- conservation of materials and energy sources;
- analysis of availability and interchangeability of all resources, such as materials, personnel, and equipment; and
- substitution of materials and energy sources with cleaner, better, cheaper, more reliable, and more readily available alternatives.

buy from local suppliers or to “buy American.” Material costs can include specialty products requiring fabrication; however, off the shelf availability of such items should be investigated to ensure that material costs are kept to a minimum. All such considerations should be evaluated early in the planning stages to ensure timely completion of the project using quality materials.

5.3.4 Supplier Manufacturing Capabilities

Specialized equipment may call for sophisticated manufacturing capabilities that are available only from a limited number of suppliers. Environmental technologies often involve this type of equipment. This can include, for example, specialized sampling equipment to monitor technology success. In order to ensure completion of the project on time, it is important that such materials and suppliers be identified at the early stages of planning and steps be taken to assess manufacturing and delivery capabilities. Project objectives should be clearly established and suppliers’ ability to meet demands evaluated. In addition, material specifications may be used to document project needs and ensure quality components are manufactured. A review of the manufacturer’s implemented quality system, as well as implementation of external quality oversight, are important. Independent oversight can be in the form of contracted experts to work with the manufacturer to provide expedited inspections and component testing, as warranted. Alternatively, the constructor can establish receiving specifications; each delivery can be inspected (typically some representative sample of each manufacturing batch for large numbers of devices) and approved before use. In the latter scenario, it is important to consider the implications to the project schedule if materials are rejected after transport. Onsite storage may be necessary to ensure an adequate supply of large-scale materials to ensure delays due to quality issues and/or transportation delays do not impact the construction schedule.

5.4 CONTRACTUAL ARRANGEMENTS

The responsible party or technology developer should establish the contracting strategy for project construction. Elements considered are the project size, the capabilities and sophistication of the local construction industry, availability of workforce, legal and political requirements, time constraints, and financing. Other key elements of contract planning and management are:

- development and control of contract documents and
- standardization of contracts.

Contractual documents usually include four basic elements: (1) bidding documents, (2) contract forms, (3) contract conditions, and (4) plans and specifications. The types of bid documents will depend on the contract mechanism and form selected. Regardless of contract type, documentation related requests for proposal, technical statement of work and specifications, qualification statements, formal bid documents, technical questions and responses, and other correspondence leading up to the selection of the constructor are part of the contract record and should be properly controlled from initiation of the bid process through completion of the project. Contract documents generally contain:

- the parties entering into the agreement,
- applicable laws and regulations,
- the effective date and duration of the contract,
- definition of terms,
- scope of work,
- addenda issued before bid submission,
- the constructor's bid,
- notice of award,
- assignment of authority and responsibility,
- performance bonds and documentation of insurance coverage, and
- any change orders or contract modifications.

Also part of the contractual record are contract conditions, including milestone and completion dates, general and supplementary conditions, terms and methods of payment, indemnifications, risks and liabilities assumed by each party, warranties and guarantees, and contract termination conditions. Plans and specifications typically include detailed design drawings for facilities to be constructed, materials specifications, specifications for construction or modification of utilities, and any other applicable drawings and specifications, such as field change orders, appropriate sign-offs at various phases of construction, and as-built drawings. Applicable legal requirements and specific administrative requirements of the site owner will dictate how long and in what form these and other contractual documents should be retained. The control of

> Applicable GEPs for constructual contracts include:
>
> - design of self-correcting procedures and processes;
> - analysis and interchangeability of all resources, such as materials, personnel, and equipment;
> - automatic communication/notification procedures and processes among all team members;
> - integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and O&M procedures and requirements;
> - integration/optimization of human, material, energy, and economic resources and logistical, political, social, environmental, and technical factors during each critical phase of the project;
> - sound project management principles/practices;
> - worker training/retraining, including hands-on training;
> - worker registration/certification;
> - certification/permitting of work procedures, processes, equipment, and environment;
> - use of automatic safety/corrective action triggers in technical, logistical, political, social, environmental, and economic situations; and
> - routine/periodic inspections, testing and compliance audits of systems, procedures, processes, and equipment, etc.

contract documents has been addressed in a joint publication, *The Uniform Locations of Subject Matter and Information in Construction Documents* (ASCE, 1981).

In order to accomplish the contracting appropriate for project construction, the lead organization should establish and maintain documented procedures for:

- defining/establishing organizational and technical interfaces;
- competitive bid, evaluation, and contract award process/procedures; and
- negotiated contracts selection and awarding procedures.

Standardization of construction contracts is desirable in order to simplify the bid process and reduce the cost of soliciting bids and responding to such inquiries (the constructor). Additionally, the use of standardized contract forms and language reduces the chance of errors and misunderstandings among the various parties. Many professional organizations and various industry associations have worked individually and jointly to develop standard forms, contracts, general conditions, and other contractual documents with this goal in mind. Examples of "standardized" contracts may be obtained from the Engineers Joint Contract Document Committee, the American Institute of Architects, and the Attorney General's Chamber. In addition, a standardized form of contractual conditions has been prepared and is widely recognized for international work. The form was prepared by the International Federation of Consulting Engineers (FIDIC) in consultation with lending institutions and constructor associations. The form can be found in *Conditions of Contract for Works of Civil Engineering Construction* (FIDIC, 1992). A guide to the use of FIDIC conditions was published in 1989 and is available through the American Consulting Engineers Council (ACEC) (ACEC, 1989).

It is important that organizational and technical interfaces be established in the contractual process and clearly defined in the contractual documents. The construction team leader establishes the project specifications and communicates them to the team members, provides commensurate funding, encourages cooperation and communication among all team members, ensures adherence to project specifications, and establishes a schedule that is adequate to complete the project in a quality fashion. In defining the project, it is critical that quality expectations be translated into clear, concise written specifications. In many cases, the design professional (or design team leader in cases involving a large design team) will assist in defining project specifications based upon agency expectations and QA and QC objectives. This process of defining project specifications may be iterative. However, it is important that they be fully defined as early as possible in the pre-design stage of the project. Ideally, the constructor's project supervisor or operations manager should be involved in these discussions so as to better understand quality expectations. However, in the case of competitive bidding, the process precludes the early involvement in defining the project specifications since competitive bidding can not be performed until specifications are fully defined.

Competitive bids are designed to provide the best value while still maintaining the goal of fairness to all parties. In order to accomplish this, two elements should be in place: (1) a clear, concise set of construction plans, specifications, contractual terms and conditions, and other contract documents; and (2) a well-defined procedure for the bid, evaluation, and award process. The contract documents clearly specify the services and product to be delivered by the constructor. The bidding procedure outlines the steps to be followed by all parties in executing the bid. These procedures protect the interests of all parties and ensure the integrity of the bidding process by establishing a step-by-step process for bid, evaluation, and award.

Negotiated contract selection may be utilized when structured competitive bids are not appropriate. In such cases, qualifications statements may be solicited and evaluated to determine the constructor best qualified to perform the desired work. Cost negotiations then proceed, generally resulting in some form of cost-reimbursable (cost-plus-fee) contract. Alternatively, fixed-price (lump-sum or unit-price) contracts may be negotiated. If more cost competition is desirable, the responsible party may select a list of qualified constructors through a pre-qualification process. The responsible party then solicits proposals from the listed contractors; the award is on the basis of proposed elements defined by the appropriate agency or contacting entity. Such elements should include:

- understanding of the project demonstrated by the constructor (based on the supplied scope of work);
- approach to the project, including utilization of unique and cost-effective approaches;
- proposed unit or lump-sum cost of the work, including fee;
- key management and supervisory personnel to be assigned to the project, including the role specified and the availability or commitment of these personnel; and
- plans and staffing to ensure compliance with safety, quality control, environmental, and other regulatory issues.

Additional elements that may be included are:

- proposed schedule with milestones and completion date;
- organization of project activities;
- use of local resources (materials, labor, etc.);
- availability of crafts, use of subcontractors, and minority and small business involvement;
- business information, such as labor and overhead costs, insurance, and contracting policies; and
- design of temporary structures, utilities, and transportation services.

5.5 PROCUREMENT

The responsible party and participating organizations, including the design professionals, construction contractors and subcontractors, and facility operators should ensure that procured products and services meet established technical and QA objectives and that they perform as specified. Prospective suppliers should be evaluated and selected on the basis of documented criteria. The responsible organization should also verify that approved suppliers continue to provide acceptable products and services. The procurement process should be controlled in accordance with Federal Acquisition Regulations for U.S. Government procurements and the issues discussed in the following subsections.

5.5.1 Planning Procurements

Early planning of and a systematic approach to procurement activities is important to ensure project quality. It is important that the organization responsibility be identified and the procurement methods, including quality control, be documented. In addition, it is important that the sequence of actions (e.g., completion of a purchase requisition will occur before supplier bids are requested or a purchase order is awarded) and applicable milestones (e.g., signatures, award date, delivery of supplies or services, etc.) be documented. Standard elements of the process should include preparation, review, and change control of procurement documents; identification and selection of procurement sources; preparation of statement of work or specifications; evaluation and award of bid or proposal; verification of receipt and acceptance of the item or service; evaluation of supplier performance; and quality assurance records. In cases where supplier performance is not of the expected level, hold-point and witness-point notifications may be required, as well as control of nonconformance and corrective action. Contractual documents should specify supplier performance expectations.

5.5.2 Selection of Supplier

Supplier selection is based upon the purchaser's evaluation of the supplier's capability to provide the items or services in accordance with the specifications established in the procurement documents. Identification of organizations responsible for supplier source selection, including the appropriate QA organization, is important to ensure that quality supplies and services are procured. Development and implementation of standardized evaluation and award procedures is also important to maintain the integrity of the selection process and ensure that supplier selection results in quality supplies and services. Supplier selection should ideally be based on an evaluation of the supplier's history for satisfactorily providing similar products and services. Alternatively, an evaluation of the supplier's QA program, including quantitative or qualitative documentation of past performance, should be performed. For example, if the supplier is providing a service such as analysis of samples collected from the site, then a pre-qualifying audit of the laboratory can be performed. In the case of suppliers that are new and do not have documentation of past performance, the supplier's technical and QA capabilities can be assessed based on an evaluation of the supplier's facilities, personnel, and quality program. In any case, it is important that the source selection be well documented. In situations where several suppliers are identified as meeting minimum quality expectations, then the competitive bid process can be used to obtain the best value. This process, however, should not be the sole basis for selection, and suppliers that do not meet minimum quality expectations should not be included as part of this competitive bid.

5.5.3 Proposal/Bid Evaluation

The bid and proposal evaluation process determines the extent to which the supplier conformed to the specifications of the procurement document (e.g., request for proposal). This evaluation is typically performed by a team of contract specialists, technical experts, and QC personnel. It evaluates the skill and experience of technical personnel; other technical considerations, such as the technical approach identified by the supplier; supplier past performance and production capability; QA program organization, procedures, and personnel; and any exceptions noted or changes in technical approach and specifications recommended by the supplier. Any such exceptions, recommended changes, or deficiencies identified during the evaluation should be resolved (or a commitment obtained from the supplier to resolve the issue) before the contract is awarded. It is important that the purchaser conduct a QA management review and accept supplier QA provisions before the contract is awarded and/or work is started.

5.5.4 Document Specifications

Procurement documents should include, where applicable to the item or service being procured, the following elements:

- A scope of work detailing the technical and administrative (e.g., progress reports) specifications.

- Other technical specifications, such as design bases (identified and referenced); design drawings and other documents (e.g., codes regulations, procedures, etc.); and tests, inspections, hold points, or acceptance criteria used to monitor and evaluate supplier performance.

- QA provisions, including: (1) QA specifications and documentation, (2) pass-down specifications that the supplier is required to incorporate into any sub-tier procurement documents, and (3) applicable QA documents from the purchaser if those are to be implemented in lieu of supplier QA procedures.

- Documentation of QA and QC procedures that may be outside normal industry standards such as those specified in a standard operating procedure. This is especially important for suppliers of services. For example, a supplier may be using a standard operating procedure that is industry accepted but may not satisfy specific project specifications. This type of situation would benefit from additional monitoring to ensure project specifications are achieved.

5.5.5 Document Review and Approval

Procurement documents should be reviewed by trained personnel with access to and understanding of the procurement scope and requirements. Comprehensive review against the document requirements ensures full compliance with procurement procedures. Assuming that these procedures have been carefully prepared, the review helps the responsible party or lead agency select the best-qualified supplier. This, in turn, optimizes the chances that appropriate and high-quality supplies are procured, thus helping to ensure that the project quality is maintained. Reviews are performed and documented, along with any changes, prior to the procurement document being issued to the supplier. Technical and QA reviews should also be performed and any changes are then approved by management.

5.5.6 Supplier Performance Evaluation Specifications

In some circumstances, it may be appropriate to require a supplier to have a quality system that conforms to a recognized consensus standard like ISO 9001:2000, *Quality Management Systems - Requirements*. In order to confirm that the supplier's quality system conforms to such standards, the supplier may demonstrate its conformity through a certification process by an independent, third-party auditor or registrar. Such certificates provide the customer with increased assurance that the supplier is capable of performing at a level that meets the needs of the customer. However, certification alone may not be sufficient to ensure that the supplier can perform to expectations in providing specific products and services. It may be necessary to assess or audit the supplier's performance directly.

5.5.7 Acceptance of Items or Services

Typically, acceptance by the purchaser of items or services received from the supplier will involve four parts:

- source verification,
- receiving inspection,
- post-installation testing, and
- supplier certification of conformance.

Source verification involves acceptance of any goods or services by the purchaser based on monitoring, auditing, or other surveillance activities performed by the supplier. Source verifications should be performed according to the supplier's inspection plans as early as possible, but prior to the activities that entail control. The extent of monitoring and the inspection intervals should be determined based upon the complexity and/or importance of the purchased item or service. Documented evidence of acceptance of the item or service is furnished to the receiving party, usually the purchaser, by the supplier. Source verification is usually performed by qualified personnel and should include involvement by the purchaser's QA organization.

Receiving inspection is used by the purchaser to accept an item in accordance with established inspection procedures, which, in turn, are driven by the established product specifications. The inspection verifies, as applicable, product identification and configuration, dimensions, physical characteristics, cleanliness, and lack of damage. Inspections also include a review of the adequacy and completeness of supplier documentation.

Post-installation testing is used to verify that an item meets the specifications of the purchaser. It is critical that the purchaser's specifications be fully documented in advance of the project and that acceptance criteria be mutually agreed upon by the purchaser and supplier. This testing can be in the form of an onsite audit of the equipment supplied. A flow meter, for example, may be tested by calibration after installation to ensure that accuracy and precision specifications meet supplier and purchaser QC specifications.

In lieu of the above acceptance methods, the purchaser may require that the supplier provide a certificate of conformance. The certificate identifies the purchased material or equipment along with the purchase order or other identification number traceable to the procurement document. This certificate should identify the codes, standards, specifications, or other procurement requirements met by the item. Any waivers, exceptions, and approved deviations or changes should be noted, along with a list of any procurement requirements not met, or each nonconforming item. It is important that this certificate be signed or otherwise authenticated by a responsible official. For example, this certificate of conformance may be American Society for Testing and Materials certification (e.g. American Society of Mechanical Engineers conformance for piping) or other similar authentication that the product performs as specified.

5.5.8 Control of Supplier Nonconformance

The purchaser and supplier should document an agreed-upon process for handling items that do not conform with procurement document specifications. At a minimum, the supplier should report nonconforming items to the purchaser within the time frame and utilizing the mechanism set up in the nonconformance procedures. The supplier should also provide the rationale for a recommended disposition of nonconforming items. The nonconformance report is to be submitted to the purchaser for approval of the recommended disposition. Alternatively, the purchaser may direct the supplier to handle the nonconforming items using an alternative method. In the case of a conflict, the two parties should negotiate based upon the framework established in the nonconformance procedures and any contractual specifications. Therefore, it is important that such procedures establish specific guidelines for handling nonconforming items. In any case, the purchaser ultimately verifies the disposition of the nonconforming items.

5.5.9 Commercial Grade Items

The design may specify commercial grade items in some cases. The items should be clearly identified in the design drawing or specifications. Any source selection specifications are also identified in the procurement document by the manufacturer's published product description. Alternative suppliers, product grades, or products may be utilized only if the purchaser approves the change or replacement. Acceptance by the purchaser will be based on verification by the design organization that the alternative commercial product performs the intended function and meets design specifications. Acceptance of commercial grade items should be based upon (1) inspection or testing by the purchaser to ensure that the item meets manufacturer's specifications, 92) verification that the item received was the item ordered, (3) confirmation that no damage was sustained during shipment, and (4) confirmation that appropriate documentation was received and is acceptable.

5.6 SCHEDULING AND TRACKING

Early construction planning by the responsible party, design professional, and constructor enables schedule milestones to be included in the construction contract. Significant issue dates for design elements and key delivery dates for supplies, materials, and factory-fabricated items should be added to the construction schedule to integrate design, procurement, and construction before construction begins. Other relevant schedule dates, such as utility hookups or changeovers should be included. It is important that the schedules be based upon labor workforce availability and realistic production rates and quantities. Equally important is that the responsible party recognizes the necessity for preparing, coordinating, reviewing, and approving shop drawings and other submittals and allows sufficient time for such reviews. Because the review process is critical to the quality process, this should be incorporated into the overall construction schedule. Schedules are expressed as bar graphs/Gantt charts for simple projects. For more complex projects, network analysis systems, such as critical path method or precedence diagramming method are recommended.

During the construction phase, the schedule is refined and expanded to include subcontractor's schedules and work activities. For long construction projects, rolling schedules are used, with periodic development of detailed schedules covering a period of several months. Schedules should anticipate possible delays, such as weather or other natural events that can prohibit certain activities. Computers can be used effectively to integrate levels of detail and individual schedules into one composite schedule. Use of uniform scheduling methods, tools, and computer software by the various parties and individuals involved in project construction, along with periodic reviews and updates, assist in effective management and control of construction activities.

5.7 COST MANAGEMENT

During the construction and fabrication of system components, the constructor's (and all subcontractors') estimates should be tracked, refined, and updated. Work productivity should also be tracked to identify problem areas. Identifying and, if necessary, correcting cost trends early in the process should help prevent overruns, quality problems, and disputes. Documented procedures should be established that will allow control and tracking of construction costs for each phase/area/activity of the construction as well as for the overall project.

Depending upon the sophistication and flexibility of the current cost-tracking system, cost tracking may be done using an existing system or new cost-tracking software may be implemented. Integration with the existing cost-tracking system is desirable from the standpoint of ease of use for the responsible party. However, if the existing system lacks the flexibility or tools necessary for a large construction project, other options should be investigated. In addition to consideration of acquiring a new or alternative cost-tracking system, the team leader should consider having cost tracking performed by the design or construction firm. Typically, large engineering and construction firms utilize cost-tracking systems that are amenable to large environmental construction projects. These professionals can maintain the project cost information and prepare either detailed or summary reports on all facets of the construction project. Frequently, the design professional will assist the team leader in tracking the labor utilization and expenses of the construction firm and the associated subcontractors. In this way, the responsible party maintains independent oversight of the constructor, yet can rely on the expertise of the design professional to maintain and track budgets and to assist in determining the legitimacy of and appropriate corrective actions to apply in cases where budgets exceed original estimates.

5.8 MATERIALS MANAGEMENT

The constructor should establish a documented plan to control and track purchasing, receiving, special storage, and in-storage maintenance of materials for the project and the time frame. The plan may include a system that will key material deliveries to the project schedules. The availability of materials should be a prime consideration any time the project schedule is revised. Productivity and quality often suffer when crews are started and stopped repeatedly due to material shortages or for other reasons. Construction materials will generally fall into one of two major classes: in situ materials and manufactured items.

In situ materials include soils and rocks used for backfill, construction bases (e.g., gravel bases for roads and foundations), or components of site structures (e.g., clay used in landfill and lagoon liners and berms, limestone in cement, or gravel in concrete). Depending upon the material requirements, these materials may be excavated at the site or may be shipped from local, regional, or national suppliers. Transport of these materials should be considered in construction scheduling, especially during severe weather. Stockpiles onsite may be used to provide a steady supply of materials; the location and footprint of such stockpiles should be considered during site planning. For large projects, rail shipment of natural materials, with local truck transfer or unload stations may be more cost effective. Some degree of testing of physical/chemical properties of natural engineering materials will typically be called for. This may be as simple as particle size analyses of aggregate or sand, which can be performed onsite using relatively inexpensive equipment and general construction staff with limited training. In other cases, more specialized tests such as compaction tests may require special laboratory equipment and staff. The location of such laboratories (onsite or offsite) will depend upon the size of the project and material specifications, as well as the availability of trained staff. This decision is project specific. Regardless, material testing is an important consideration in the overall schedule and quality of the project. QA procedures should address acceptance criteria and supplier contracts sufficient to document disposition procedures for off-specification materials. Ideally, initial material testing is performed at the supplier location with additional quality checks at the receiving site. One important note is that the physical properties (especially density and particle size) of many construction materials can be affected by pneumatic and conveyor loading/unloading systems as friable particles are broken down due to friction. Therefore, the supplier tests and the receiver tests may yield slightly different results. It is important that contractual documents address this issue so that materials of the correct specification can be supplied according to schedule commitments without delays for disputes over material quality.

Manufactured items include a wide variety of materials. Examples include metal or plastic piping; paints and sealers; liners or other plastic products; structural steel; electrical conduit, wiring, circuit breaker, switches, and other electrical components; motors, pumps, and other mechanical installations; plywood, particle board, and other wood and timber products; brick and other masonry products; and asphalt. As with in situ materials, identification of suppliers, establishment of contractual relationships, development of quality specifications, and consideration of schedule are all important elements of material management. Materials quality specifications may be established by broadly-accepted standards developed by organizations, such as the American Society for Testing and Materials, the American Concrete Institute, Institute of Electrical and Electronic Engineers, and so forth. Alternatively, site-specific standards may be developed by the design firm. A good list of acceptance standards for a variety of materials is presented in the American Society of Civil Engineers guide, *Quality in the Constructed Project: A Guide for Owners, Designers and Constructors* (ASCE, 2000).

5.9 LABOR/WORKFORCE MANAGEMENT

Labor and workforce management may be the most critical element of the construction phase of the project. The constructor should determine the number of people required by craft and special skills and determine the availability of workforce to meet needs. A clearly defined and coordinated strategy for meeting the labor and workforce needs is therefore crucial. Because construction labor is usually subcontracted locally, a connection with the local business community should be established. This is particularly important because the responsible party or agency who is in charge of constructing the technology may be from outside the immediate area.

In cases where localized labor shortages exist or shortages in certain labor categories exist, a number of strategies may be applied to expand the workforce pool. Incentives, such as higher wages, signing bonuses, relocation expenses, per diem living expenses, and overtime schedules are potential alternatives. Training new employees in certain tasks may be cost effective, especially for projects with longer duration. Alternatively, having construction/fabrication work performed offsite could be considered. In this way, skilled labor can be utilized without the additional expenses of premium pay or training programs. Typically, the decision of whether to use onsite versus offsite labor is based upon the availability and skill of the respective labor pools. Cost considerations should account for transportation costs of offsite materials as compared to the aggregate labor costs (including training, shift premiums, bonuses, etc.) of onsite labor.

5.10 SAFETY MANAGEMENT

The constructor is normally responsible for planning and execution of a safety and first-aid program. The program is structured to comply with federal, state, and local laws and regulations. Job-site or project-specific plans may include:

- appointment of a site safety officer with responsibility for developing and/or implementing the safety program;
- development of safety procedures for chemical, mechanical, electrical, as well as other general work place and site-specific hazards;
- conducting safety training sessions before site activities begin with updates on a regular basis or in response to safety concerns, violations, or accidents;
- posting safety rules and enforcement actions;
- posting of emergency telephone numbers;
- supplying or defining the requirement for employee or subcontractor safety equipment; and
- identifying and posting escape routes and rallying areas (for head count) in case of emergency.

Other planning and management activities may include site environmental control, hazardous waste handling, traffic control, site security and access, and public relations. All safety management issues taking place during construction should be coordinated with an overall site health and safety plan.

5.11 INSPECTION, TESTING, CONTROL, AND TRACKING

Inspections and testing should be performed in accordance with approved procedures. An important part of the work planning process is to identify the items and processes to be inspected or tested, the parameters or characteristics to be evaluated, the techniques to be used, the acceptance criteria, any hold points, and the organization responsible for performing the tests and inspections. Inspection and testing of specified items and processes are conducted using established acceptance and performance criteria. The acceptance of items and processes are made by and documented by qualified and authorized personnel. It is important that equipment used for inspections and tests be calibrated. An inspection and testing programs for the construction/fabrication/installation of environmental technology should be in accordance with the following key specifications.

First, it is important that a planning program be implemented for the inspection, testing, and monitoring of materials. Several objectives should be considered:

- the quality of supplies should be verified in accordance with specified procedures,
- the inventory of supplies and materials should also be monitored to ensure the continuity of construction activities, and
- the workmanship and adherence to technical specifications should be verified for specially-fabricated materials and equipment.

Secondly, a thorough and comprehensive inspection, testing, and monitoring program should be implemented. This may involve the inspection of supplies and materials in process at the supplier location. Alternatively, inspections may be made of goods ready for shipment from the supplier or as received by the constructor or his/her contractor. Additional inspections and testing may be performed when the supplies or equipment are in service to ensure that construction and operational specifications are being met. Typically, this type of inspection would be performed to supplement in-process or receiving inspections; in rare cases, it may be used as the only inspection and testing mechanism.

Thirdly, the performance of inspections and testing, as well as the results, should be fully documented. This is critical in cases where problems and defects occur and there is a disagreement between the receiver and the supplier as to the quality of the product or material. Since such problems cannot be predicted, it is important that thorough documentation be an integral part of the inspection and testing process.

Finally, a quality assurance program is vital to the inspection and testing program. It is important that any monitoring, measuring, testing, and data collection equipment be properly selected and utilized. Equipment selection entails that the equipment measure the parameter within the established acceptance range. Therefore, the testing equipment should be properly sized such that its measurement range and accuracy meets that established for the product or material. In addition, the testing equipment should have a precision range that encompasses the agreed-upon tolerance limits for the product. As has been discussed previously, the acceptance range and tolerance limits should be established in advance, agreed upon with the supplier, and fully documented in the appropriate contractual documents. Not only should the measurement instrument be properly selected, it should be properly used and controlled to ensure the reliability of testing results. The equipment should be used according to the manufacturer's instructions for that equipment. If use is under harsh conditions at the construction or manufacturing site (e.g., extremely dusty conditions or temperature extremes), the equipment may not perform according to manufacturer's specifications. At a minimum, additional maintenance of the testing equipment will likely be called for. Frequent performance and documentation of equipment calibration is important, especially under harsh operating conditions. Zero checks and calibration with known standards are typically the minimum calibration specifications. Additional calibration procedures may include measurement of internal standards (standard incorporated into the matrix to be measured) or other more sophisticated QA procedures. Equally important to the selection and calibration of testing equipment are the qualifications of inspection and test personnel. Training in inspection and testing procedures, equipment use and calibration, and proper procedures to document inspections and tests is critical to the success of any quality assurance program.

5.12 COMPLETION APPROVALS

Environmental technology construction projects may have two levels of approvals: (1) internal and (2) external/independent/regulatory. Internal certifications and approvals consist of the design professional verifying/authenticating and certifying for the responsible party the completion of part or all of the construction/fabrication/installation. Large segments of construction, specialized and/or expensive equipment, or critical path items may be certified before the entire project is completed. This approach is especially appropriate if the remainder of the construction project relies heavily on these components or installations. Examples of such equipment might be stand-alone utilities or boilers; berms, dikes, lagoons, culverts, or other surface water management structures; or foundations for the installation of other equipment. In some cases, external or independent certifications and approvals may be required. Approvals may include local building or health inspectors. Other independent oversight may be required by insurance firms or loan institutions, depending upon their specifications. When a project is completed (or critical portions thereof), many agencies require some sort of release or affidavit, or both, certifying that work has been done substantially in accordance with the contract documents and that no outstanding payments are due. Furthermore, information on the location or completeness of record drawings and certain project-specific design/construction documents may be required. In addition to formal regulatory review, environmental projects involving other stakeholders (e.g., local communities, environmental groups, etc.) may require approval by these stakeholders or their technical representatives.

During the planning phase of the project, specifications for construction completion certification and approvals of external agencies and other groups should be established, documented, and communicated with appropriate individuals/organizations involved. Based on the external certification and approval requirements, the owner may establish procedures for the internal certification and approval by the design professional.

CHAPTER 6

SYSTEM OPERATION AND MAINTENANCE

6.1 INTRODUCTION

This chapter discusses:
- planning for O&M input and training;
- O&M considerations during the design phase;
- O&M considerations during the construction/fabrication/installation phase;
- system start-up;
- normal/routine operations;
- inspection and testing;
- handling, storage, packaging, preservation, and delivery; and
- emergency/contingency management.

The operational characteristics and maintenance of the project after completion and turnover to the owner determine the success in meeting project objectives. O&M factors influence life-cycle costs, continuity of service, durability, public health and safety, environmental impact, and other features of the completed environmental technology project/program/facility. Consideration of O&M specifications in each phase of project planning, design, construction, and start-up is desirable. Environmental technologies should be operated in accordance with approved design documentation and operating instructions and guides.

For all projects, active participation of the developer from an O&M viewpoint adds to the developer's understanding of the design criteria and the effort to translate the design professional's contract documents into an operating facility meeting project specifications. Typically, the developer is responsible for O&M after the facility is completed. To implement quality operation and maintenance activities, the involvement of experienced operators is desirable. To this end, the developer may designate an O&M representative to advise and assist the design professional and constructor in planning, designing, and constructing the facility with O&M consideration in mind. In the planning and design of the project, the O&M concern is with input to and review of design-phase activities; in the construction phase, the concern is with construction observation and inspection; in the start-up phase, the concern is with verification, testing, and acceptance; and in the operational phase, the concern is with the operation and maintenance of the constructed project.

O&M procedures are normally established and documented to ensure control and compliance for each of the various stages of the project as discussed below.

6.2 PLANNING FOR O&M INPUT AND TRAINING

The developer, when making contractual arrangements for the project, may select from a number of options in providing for consideration of the various O&M issues as they influence design, construction, and operation of the environmental technology.

- The developer may appoint a member of the O&M staff as project coordinator to advise the design professional and the constructor from the O&M standpoint. For this assignment the developer should find an experienced individual, preferably a candidate to head up the operations team for the completed facility. The team leader would be responsible for planning, developing, and coordinating the appropriate project-specific training programs.

- The developer may contract with the design professional to have an experienced professional member of the design team or a qualified consultant provide the appropriate O&M advice and review.

- The developer may delegate members of the O&M staff to work under the RPR or the design professional in observation and/or inspection of construction activity during the construction phase. This assignment provides an opportunity for O&M personnel to become familiar with the project while performing construction phase duties.

- The developer may delegate members of the O&M staff as well

Planners and coordinators should incorporate the following GEPs in the designing, planning and managing of the constructed environmental technology O&M program:

- fail-safe/intrinsically safe design of procedures, processes, equipment, structures, and facilities;
- flexible, built-in designed procedures, processes, equipment, structures, and facilities;
- design of self-correcting procedures and processes;
- reuse of materials required for technology operation or development;
- reduced use of virgin materials, wastes generated, energy sources, and human resources;
- recycling/recovery of materials, utilities, and energy sources;
- conservation of materials and energy sources;
- analysis of availability and interchangeability of all resources, such as materials, personnel, and equipment;
- substitution of materials and energy sources with cleaner, better, cheaper, more reliable, and more readily available alternatives;
- use of commercially available and tested materials, products, processes, equipment, and supplies;
- computerized/remote control of unit operations and processes;
- automatic communication/notification procedures and processes among all team members;
- integration of planning, design, purchasing/procurement, fabrication, construction/installation processes, and O&M procedures and requirements;

as the O&M coordinator to work with the design professional and constructor during the start-up phase of the project.

- The developer may contract with the design professional and/or constructor to provide review of and advice for operation and maintenance programs for some defined time after the project has been taken over by the operating staff.

Specific O&M related roles of the design professional, constructor, and O&M coordinators or advisers should be clearly defined in the developer/designer agreement and the developer/constructor contract as these roles are influenced by O&M considerations.

6.3 O&M CONSIDERATIONS DURING DESIGN PHASE

Decisions made during the design phase relating to site selection and access, process choice, equipment selection, and other elements of the project will impact O&M of the completed project and limit flexibility in subsequent phases of the project. Therefore, O&M coordinators and advisers should be consulted for choices of brands or models of equipment selected, arrangements of facilities, access for equipment repair, and other design features that influence O&M management, costs, and activities.

(GEPs for O&M program continued)
- integration/optimization of human, material, energy, and economic resources and logistical, political, social, environmental, and technical factors during each critical phase of the project;
- worker training/retraining, including hands-on training;
- worker registration/certification;
- certification/permitting of work procedures, processes, equipment, and environment;
- automatic shutdown of systems, equipment, and processes;
- use of automatic safety/corrective action triggers in technical, logistical, political, social, environmental, and economic situations;
- use of interlocks as safety measures;
- use of lockout/tagout procedures and equipment during systems fabrication/installation and operations;
- prevention of calamities through process hazard analysis, HAZOP, FMEA, fault tree analysis, and incident investigations; and
- routine/periodic inspections, testing, and compliance audits.

Reviews stressing the operability and maintainability of various features of the project are scheduled at appropriate points in the design phase and at final design. The frequency and depth of these reviews vary with the size and complexity of the technology to be deployed. Reviews from an O&M perspective normally include the following:

Physical plant considerations – size and layout of working space to be provided; suitability of equipment types, including efficiency in operation, maintenance schedule, and costs for the equipment; provisions for bypassing and isolation equipment for maintenance; specialized services, such as laboratory and chemicals; staff amenities, such as cafeteria, meeting rooms, and shower facilities; adequate lighting and ventilation; future expansion requirements; modular expansion possibilities; efficient land utilization; specific layout of equipment, process, and control systems to provide O&M accessibility; proper location of hoists; access for moving materials; lay-down space and removal paths; appropriate flexibility and redundancy in equipment and controls; and provision for adequate manufacturer-supplied materials, training, and spare parts information.

Control strategies – manual backup controls proposed for use and the effects of alternative strategies on efficiency of operations and staffing.

Life-cycle cost considerations – building materials and equipment.

Environmental considerations – provisions to mitigate odors, noise, and undesirable aesthetic effects, as well as the possible need for a public-relations program.

Safety considerations – equipment, chemicals, protective devices, sprinklers, clothing, and staff training.

Personnel and budget planning for O&M staffing – of the proposed facility and a tentative budget and staffing plan.

During the design phase, the developer is responsible for communicating needs, constraints, expectations, and requirements regarding performance, operation, and maintenance of the proposed facility and for providing timely reviews. The developer is also responsible for providing adequate O&M input and determining (with the help of the design professional and the O&M coordinator) O&M budget and staffing requirements and for initiating the hiring of supervisory personnel during the latter part of the design stage.

The design professional is then responsible for preparing the plans and specifications incorporating O&M considerations. The design professional includes in the construction contract documents provisions for equipment performance criteria, repair and replacement warranties, adequate manufacturer-supplied O&M manuals, spare-parts information, operator training on new or complex equipment, and equipment start-up specifications. The design professional is frequently authorized to prepare an O&M manual to include items such as process description, design criteria and equipment data, equipment purpose, operating parameters, potential problems and solutions, emergency operating procedures, safety, and other information. Plans and specifications, including backup documentation prepared by the design professional, constructor, or vendor are made available for O&M use.

6.4 O&M CONSIDERATIONS DURING CONSTRUCTION/FABRICATION/ INSTALLATION PHASE

The construction phase of the project provides an opportunity for the developer's O&M coordinator and staff to make the transition from the advisory and review activities of the design phase to more active roles during the construction phase. Activities contributing to project construction that can also provide valuable information and training for O&M personnel include:

- inspection and testing of materials and equipment, onsite and at the manufacturer's site;
- observation of installation and testing of equipment by the constructor;
- observations of construction activities pertaining to utility routing and locations, installation problems affecting O&M and arrangements of project elements as they affect operational safety and maintenance;
- assistance to the contractor in assembling documentation specified under the construction contract; and
- assistance to the design professional in preparation and review of the O&M manuals and procedures by the design professional.

These activities and others of a similar nature can be performed strictly as a training exercise, or they can be performed by members of the RPR's field staff, or by members of the design professional's field staff during the construction phase. If members of the O&M staff are to function as part of the design professional's staff, the developer/designer agreement should be written to clearly define lines of authority and responsibility for this situation.

The constructor's responsibilities relating to O&M include:

- assembling and forwarding to the developer information specified by the contract documents on various pieces or assemblies of equipment, including manufacturers' warranties, operating instructions, and maintenance specifications;
- maintaining a current set of revised plans and specifications, including the effect of change orders and other pertinent information to guide the design professional in preparing record documents for the facility;
- coordinating with the O&M staff on delivery and storage of spare parts, tools, and equipment to be used for project O&M; and
- working with the O&M coordinator and design professional in planning for and conducting project start-up.

During the construction phase of the project, the constructor is responsible for the acceptance-testing of various elements as specified in the contract documents and for the maintenance of these elements until turnover to the developer for operation. The constructor's role in project start-up and turnover varies from project to project and is defined by terms of the owner/constructor contract.

6.5 SYSTEM START-UP

The purpose of start-up phase activities is to demonstrate that project elements constructed or installed by the constructor are in working order, and that the facility performs as planned by the developer and the design professional. This activity gives the O&M staff the opportunity to become familiar with the project under the guidance of the constructor and design professional. Start-up and turnover of an environmental technology may require the organization and training of a start-up group composed of representatives from the developer, design professional, and constructor. The developer's O&M staff are key players in the start-up of any project.

6.5.1 Planning the Start-up Program

Responsibility for organizing and leading the start-up program is generally addressed in the developer/designer agreement and owner/constructor contract and may be assigned to:

- the design professional on projects where the design professional has responsibility for drafting the O&M manual and for training O&M personnel;
- the constructor on design-build or turnkey projects; or
- the developer, on industrial projects where the developer may have furnished or specified the process equipment, on projects using multiple constructor and design professional assignments for elements of the total project, or on expansion (scale-up) or remodeling (retrofit) projects when joint occupation of the site entails close coordination of construction and O&M activities.

With responsibility for start-up established, the start-up team is assembled with representation from the design professional, constructor, and developer, with particular emphasis on representation from the developer's O&M staff. Activities of the team in planning for start-up include:

- preparing and reviewing start-up programs and procedures,
- determining construction completion status,
- planning for supervision of system testing and correlation of deficiencies, and
- reviewing final inspection reports and project closeout submittals.

Planning for an environmental technology/treatment system/facility start-up calls for a well-defined approach and documented procedures and methods for:

- HAZOP review/analysis,
- safety checking/testing,
- operator and supervisor training,
- system start-up (start-up procedures),
- standard operating procedures, and
- emergency shutdown procedures.

The interaction and exchange of information among the principal parties involved in the project may be outlined in a start-up manual along with planning, scheduling, testing, and other activities planned by the start-up team. Start-up manuals should be structured to fit the project. Simple, direct, and brief language is preferred. Aids, such as forms, checklists, and tabulations are useful.

6.5.2 Start-up Activities

Project start-up activities demonstrate the integration of various constructed systems into a unified facility. Major systems that eventually constitute an environmental facility are grouped into the following categories:

Structure – consisting of foundations, slabs, bearing walls, and frames.

Envelope – consisting of roofs, curtain walls, and ceilings.

Life safety and habitat support systems – further divided into two categories: mechanical systems that provide water supply, waste disposal, heat transfer, conveyances, and fire safety and electrical systems that supply power and are tied into the mechanical system.

Process systems – utilizing specialized equipment supported by the mechanical and electrical systems for treating the target environmental matrices and residuals.

Interior – or architectural details of habitable facilities such as an onsite office/administrative building or trailer.

Exterior – consisting of parking lots, pedestrian access, landscaping, storm water drainage, utility, and transport systems.

Accomplishing a smooth project start-up involves the same effective planning and scheduling techniques as did earlier stages of the design and construction process.

Start-up activities are generally based on the premise that project elements completed by the constructor have met the material, workmanship, and performance specifications contained in the owner/constructor contract. The start-up activities are structured to:

- determine that each component of the project is in working order;
- determine that these components can be integrated to operate as a facility, which performs as planned by the developer and design professional;
- provide a means of training O&M personnel in the operation of each of the components and of the completed facility (O&M during the start-up of the project provides opportunity for the O&M staff to view technology operations with guidance from the design professional and the constructor);
- validate O&M instructions and manuals prepared by the design professional or others;
- check the file of record documents (plans, specifications, manufacturers' operating instructions, maintenance instruction, etc.) for appropriate scope and detail; and
- serve as a vehicle for acceptance of the constructor's completed contract and turnover of the facility to the developer's O&M staff for operation.

6.6 NORMAL/ROUTINE OPERATIONS

The post-construction, post-start-up operating phase of the project is generally the sole responsibility of the developer or oversight agency and the O&M staff (which can be a service contractor). During the early months or the first year or two of the operation of the environmental technology, the O&M staff works with and/or through the constructor in seeking enforcement of all applicable warranties (and performance standards) and correction of any defects found in the constructor's work during the warranty period as defined under the developer/constructor contract. The O&M staff may also wish to consult with the design professional to request clarification and amplification of operating and maintenance manuals, to seek advice in fine-tuning project operations, and to ask for assistance in testing and evaluating performance for conformance to design criteria and project specifications.

Documented procedures should be established prior to the start of the operating phase and refined, fine-tuned, and updated, as needed, for all substantial activities that constitute the system operation, such as the following:

Process control and monitoring – to ensure that process output (the product or discharge stream) complies with reference standards/codes, quality plans, and/or documented procedures, and stays within the permissible tolerance criteria.

Equipment control and maintenance – to ensure that each piece of equipment within a process, process train, or system performs its intended task with the appropriate degree of accuracy and reliability.

Utilities management – equipment and procedures for materials handling, storage, packaging, preservation, and delivery.

Technology operating guides provide helpful information about systems and processes. They normally include, but are not limited to:

- appropriate controls for materials (including consumables) and measuring and testing equipment;
- configuration management;
- operating procedures and parameters for specific components and system configurations, including specified safety limits;
- process equipment control and maintenance, including during abnormal conditions for inspection and test solutions for fault and emergency conditions;
- special environments, time, temperature, or other factors affecting the quality of operation; and
- the skill, capability, and knowledge of operators to meet operational, environmental, and quality objectives.

6.6.1 Process Control

Process control activities may be documented by instructions, procedures, drawings, checklists, or other appropriate means. These means ensure that process parameters are monitored and controlled and that specified environmental conditions are maintained.

6.6.2 Control of Auxiliaries and Services

When the quality of systems operation is directly affected, auxiliary materials, utilities, and consumables (e.g., water, compressed air, electric power, chemical feed stocks) should be controlled and verified periodically to ensure uniformity of their effect on the systems involved in accordance with established procedures. Only qualified and accepted services or items and consumables should be used during the operation of systems.

6.6.3 Control of Operational Status

The status of the operating system is controlled to ensure conformance with the approved operating procedures and specifications. Status indicators with tolerance limitations should be provided to display the operating status of systems and components of systems as described in the design and operating instructions and guides. The use of status indicators will help to prevent inadvertent operation or removal from operation of any systems or components when such actions would adversely affect performance of the systems, constitute an operational safety or environmental hazard, or violate statutory/regulatory compliance requirements.

Note: Such situations include the loss of data that are difficult or impossible to reproduce and may result in the unplanned release of pollutants in excess of established limits.

6.7 INSPECTION AND TESTING

The O&M organization should establish and maintain documented procedures for receiving, in-process, and final inspection and testing to order to verify that specifications are achieved. Provided in this section are inspection and testing specifications for engineering applications. Also included in Chapter 7 are specifications for onsite audits or assessments. Areas of inspection include:

- equipment, parts, spare parts, system components, hardware, software and supplies;
- process feed/inputs;
- other processing materials; and
- treated materials and products/by-products.

Inspections and testing should be performed in accordance with approved, documented, and implementable procedures. An important part of the work-planning process is to identify the items and processes to be inspected or tested, the parameters or characteristics to be evaluated, the techniques to be used, the acceptance criteria, any hold points, and the organizations responsible for performing the tests and inspections. When a sample is used to verify acceptability of a group of items, the sampling procedure is based upon recognized standard practices. Inspection for acceptance should be performed by personnel other than those performing or directly supervising the work being inspected. Inspection and testing of specified items and processes is normally conducted using established acceptance and performance criteria. The acceptance of items and processes is then documented by qualified and authorized personnel. Equipment used for inspections and tests should also be calibrated and maintained.

6.7.1 Qualifications of Inspection and Test Personnel

Each person who verifies conformance of O&M activities for purpose of acceptance should be qualified to perform the assigned inspection task. Inspections by persons during on-the-job training for qualification should be performed under the direct observation and supervision of a qualified person and verification of conformance should be made by the qualified person until certification is achieved.

6.7.2 Inspection and Testing Specifications

A. Planning for Inspection and Testing

Inspection is not a QA function. It is a line implementation function and test planning should be performed and documented. This includes:

- identification of the item to be tested or the treatment processes/operations where inspections are necessary;
- identification of the test specifications or the characteristics to be inspected and the identification of when, during the treatment process, inspections are to be performed;
- identification of the testing, inspection, or process monitoring methods to be employed;
- identification of acceptance criteria, including the desired levels of precision and accuracy;
- identification of sampling activities;
- methods to record inspection or test results;
- selection and identification of the measuring and testing equipment to be used to perform the test or inspection;
- process used to ensure that the equipment being utilized for inspection or testing is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function;
- provisions for ensuring that prerequisites for the given test or inspection have been met, including hardware and software needs, personnel training and qualification, and suitably controlled environmental conditions; and
- any mandatory hold points.

When statistical sampling is to be used to verify the acceptability of the subject items or materials, the statistical sampling method is based on recognized standard practices.

B. Receiving or Hold Point Inspection and Testing

The O&M staff should ensure that incoming materials or products are not used or processed until they have been inspected or otherwise verified as conforming to specifications. Verification of the specifications is performed in accordance with the project-specific quality plan and/or documented procedures. When incoming material or product is released for urgent treatment/processing purposes prior to verification, it should be positively identified and recorded in order to permit immediate recall and retreatment in the event of nonconformity to specifications.

Hold points are used to control work or activity that is not to proceed without the specific consent of the designated representative or organization placing the hold point. The specific hold points should be specified in appropriate documents. Only the organization or representative responsible for the hold point may waive the hold point inspection requirement. Consent to waive specified hold points is recorded prior to continuation of work beyond the designated hold point.

C. In-Process Inspection and Testing

Items or materials in process (of treatment) are inspected and/or tested as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing/treatment methods, equipment, and personnel should be provided. When a combination of inspection and process monitoring methods is used, monitoring should be performed systematically to ensure that the specifications for control of the process and the quality of items are met throughout the duration of the treatment process.

Controls should be established and documented for the coordination and sequencing of the work at established inspection points during successive stages of the treatment process.

D. Final Inspection and Testing

Final inspections include a review of the results and verification of the resolution of all nonconformities identified by earlier inspections. Treated materials are inspected and tested for completeness or other characteristics as required to verify the quality and conformance of the materials to the applicable specifications. Records review is performed to ensure adequacy and completeness. Reprocessing or further treatment of the treated materials subsequent to final inspection normally entails reinspection or retesting, as appropriate, to verify acceptability.

E. In-Service Inspection and Testing

In-service inspection or surveillance of structures, systems, or components of the environmental technology should be planned and executed by or for the organization responsible for their operation. Inspection and testing methods should be established and executed to verify that the characteristics of the subject material continue to remain within specified limits. Inspection and testing methods includes evaluations of performance capability of key emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

F. Inspection and Test Documentation

The O&M organization should establish and maintain records that provide evidence that the components and processes of the environmental technology and the materials involved, including the feed matrices, treatment chemicals and supplies, and the treated residuals, have been inspected and/or tested. These records should clearly indicate whether the subject item has passed or failed the inspections and/or tests according to defined acceptance criteria. Inspection and test results are then evaluated by qualified individuals within the O&M organization to ensure that all test and inspection specifications have been satisfied. When the item fails to pass any inspection and/or test, the procedure for control and replacement of the nonconforming item would apply. Inspection and test documentation should identify:

- items or materials inspected and/or tested;
- the date of inspection and/or test;
- the name or unique identifier of the inspector/tester who documented, evaluated, and determined acceptability;
- the method of inspection and/or the applicable test specifications, plans and procedures, including revisions;
- the inspection and/or test criteria, sampling plan, or reference documents (including revision designation) used to determine acceptance;
- the results;
- the identification of the measurement and testing equipment used during the inspection and/or test, including the identification number and the calibration due date; and
- reference to any information on actions taken in connection with nonconformities, as applicable.

6.7.3 Control of Measuring and Testing Equipment

The O&M organization should establish and maintain documented procedures to control, calibrate, and maintain inspection, measuring, and testing equipment (including testing software) used by the supplier to demonstrate the conformance of the item to the specifications. Inspection, measuring, and testing equipment are used in a manner that ensures that the measurement uncertainty is known and is consistent with the measurement capability.

When testing software or comparative references such as testing hardware are used as suitable forms of inspection, they should be checked to prove that they are capable of verifying the acceptability of the item or material, prior to the release for use in the installation and servicing of the environmental technology or during the treatment process, and then rechecked at prescribed intervals. The O&M organization should establish the extent and frequency of such checks and then maintain records as evidence of control.

6.7.4 Inspection and Test Status

The inspection and test status of an item should be identified by suitable means, which indicates the conformance of the item with regard to inspection and tests performed. The identification of inspection and test status should be maintained, as defined in the project-specific quality plan and/or documented procedures, throughout the operation and maintenance of the treatment process to ensure that only items and materials that have passed the inspections and test (or released under an authorized concession) are used, installed, or dispatched.

6.8 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

Documented procedures should be established and maintained for handling, storage, packaging, preservation, and delivery of product.

Handling – the O&M organization should provide safe and proven methods for handling products in order to prevent damage or deterioration.

Storage – designated storage areas or stock rooms are used to prevent damage or deterioration of product, pending use or delivery/dispatch/release. Appropriate methods for authorizing receipt to and dispatch from such areas should be stipulated. In order to detect deterioration, the condition of product in storage should be assessed at appropriate intervals.

Packaging – packing, packaging, and marking processes (including material use) should be controlled to the extent necessary to ensure conformance to specifications.

Preservation – appropriate methods for preservation and segregation of products should be applied when the product is under the control of the facility owner or its representative.

Delivery – the O&M organization should be responsible for the protection of the quality of product after final inspection and testing. When contractually specified or mandated by regulation, this protection is often extended to include delivery or transfer to destination.

6.9 SYSTEM PERFORMANCE ASSESSMENT AND RESPONSE

Work performed during the design, construction, and operation of environmental technology that affects quality should be assessed regularly to ensure that approved planning, design, and operating guidelines are being implemented as prescribed. When acceptance criteria are not met, deficiencies should be resolved and reassessments conducted as necessary. Appropriate corrective actions can be taken and their adequacy confirmed, verified, and documented in response to deficiencies or nonconformities. Elements pertaining to assessment and response of the O&M program are discussed in Section 7.

6.10 REGULATORY AND TECHNICAL COMPLIANCE

The performance of an environmental technology (and system components) should be verified for compliance to its intended use as specified in the approved design specifications (or other planning documents, such as operating permits). Regulatory and technical compliance is accomplished through specific and targeted inspection, testing, review, certification, and documentation programs (discussed earlier). These compliance programs are normally conducted prior to and after installation at prescribed intervals, as may be required by certain permits or design specifications.

6.11 EMERGENCY/CONTINGENCY MANAGEMENT AND RESPONSE

During construction and operation of an environmental technology, depending on the nature, location, and design of the project, potential risks are present. These risks can be broadly classified as:

- risk of damage to public health and safety,
- risk of environmental damage,
- risk of personal injury to project workers during construction and operation, and
- risk of property damage or loss.

The mere presence of these risks may not directly impact the quality of design, construction, and operation of an environmental technology. However, the planning and managing of these emergencies/contingencies may indirectly or inadvertently impact quality. Therefore, wherever applicable, designers, constructors, and operators of an environmental technology should consult and/or coordinate their respective activities with the appropriate professionals and/or organizations. Typically they may include the following teams:

- Organization and Planning for Emergency Response,
- Emergency Response (ER),
- ER Equipment and Materials,
- ER Training and Certification, and
- ER Readiness Review and Documentation.

CHAPTER 7

ASSESSMENT AND VERIFICATION

7.1 MANAGEMENT/TECHNICAL ASSESSMENT AND RESPONSE

This section summarizes the role of assessments in environmental technology projects, and how the results of assessments are used. For more information on how to conduct technical audits and assessments, see *Guidance on Technical Audits and Related Assessments (EPA QA/G-7)* (U.S. EPA, 2000c).

This chapter discusses:

- management and technical assessment and response, including types of assessments, control of nonconforming items, and corrective and preventive action, and
- verification and acceptance, including verification tools and reconciliation of as-designed and as-constructed projects.

7.1.1 Types of Assessments

Work performed during the design, construction, and operation of environmental technology that affects quality should be assessed regularly to ensure that approved planning steps, design specifications, and operating guides are being implemented as prescribed. When acceptance criteria are not met, deficiencies are normally resolved and reassessments conducted as necessary. Appropriate corrective actions are taken and their adequacy confirmed and documented in response to deficiencies or nonconformities. Under most circumstances the organization performing assessments has sufficient authority and freedom from the activities being assessed to carry out its responsibilities. Persons conducting external or third-party assessments should also be technically qualified and knowledgeable of the items and activities being assessed. In addition, the owner/developer may have a need to conduct internal or first-party assessments.

The types and frequencies of independent assessments are usually based upon the relevant control levels assigned to the items and activities under the cognizance of the organization. In addition, the participant organizations responsible for the performance of activities important to compliance application, waste characterization, or the isolation of waste within the disposal/treatment system should implement a program of surveillance and audits. The program is then planned and documented and should include both routine surveillance of those activities and audits to establish compliance with all aspects of the project-specific QA plan and to determine its adequacy and effectiveness.

Periodic assessments or audits may also be desirable throughout the process life cycle. Audit timing should be addressed. Is a process audited only once at the beginning, periodically throughout its life cycle, or perhaps when changes in operation or personnel occur? Selecting qualified personnel for audits is important to the success of the audit. Personnel should be chosen based on two primary factors: (1) the expertise appropriate to review the process or operation being audited and (2) experience in performing audits. Oftentimes, a team approach is appropriate to provide these qualifications. In many instances a technical expert and QA auditor can work together to provide the combined expertise suitable for the audit. This is particularly useful during technology operation or evaluation. This approach would usually be applied as part of a technical systems audit conducted early in the operation life cycle. Technical experts can provide invaluable expertise in evaluating design, construction, and operation of environmental technologies. The technical expert provides the knowledge and experience adequate to address all parts of the process audited. The QA auditor provides the understanding of the audit process, helping to focus the audit on those activities that are most critical. The QA auditor can also provide leadership in terms of how to frame questions, what type of follow-up questions might be appropriate, and how to couch audit findings so as to maximize management support. Audit procedures and checklists should be developed and reviewed by the team before beginning the audit. Thought should be put into the process flow (beginning with receipt, testing, and acceptance of materials, through operational aspects, and ultimately ending with the finished product or completed project). Audit questions should be clear, concise, and nonjudgmental. Potential follow-up questions should be anticipated and, where appropriate, decision trees applied. Another important aspect of audit planning is addressing the issue of responsibility or authority to suspend work if audit findings show that the process is out of compliance with regulatory or QA criteria. Should the process be halted or operational changes evaluated if deficiencies are noted during the course of an audit? Serious findings may be identified. How are they reported? How are they brought to the attention of appropriate personnel? When should work be suspended for re-assessment?

Basic assessments include quality control or technical assessments and management audits. These assessments are designed to provide a review of project performance that is unbiased by the pressures of meeting construction schedules and budgets. An example of a quality control assessment is the **technical systems audit**. This is an audit of systems to ensure that procedures defined in planning documents are being carried out properly. The project planning document should be used as a guide when performing these assessments.

Management audits and assessments, on the other hand, are evaluations of program or project management quality. These are performed by managers, or designated internal or external experts, to periodically assess the performance of their organizations. Examples include financial audits, audits of contract and subcontract records, and environmental audits. The results of these audits should be used to implement corrective measures, where necessary, and as input into the organization's continuous improvement process. In many cases, such assessments are an integral part of management review.

Surveillances are a type of technical audit involving observation of a specific technical activity on an extended basis. The surveillance process consists of monitoring or observing to determine whether an item, activity, system, or process conforms to specifications. Surveillances are intended to accomplish the following:

- monitor work in process,
- document compliance or noncompliance with established specifications and procedures,
- identify actual and potential conditions adverse to quality,
- obtain timely corrective action commitment from cognizant managers for identified conditions adverse to quality,
- provide notification to responsible managers of the status and performance of work under surveillance, and
- confirm timely implementation of corrective action.

Assessments should be performed using the written procedures related to the activity being assessed. Elements that have been selected for assessment are then evaluated against specifications. Objective evidence is obtained to determine if those elements are being implemented effectively. Audit results are normally documented by audit personnel and reported to and reviewed by management with responsibility for the area audited. Conditions requiring prompt corrective action should be reported immediately to management of the audited organization. Conditions adverse to quality should also be documented and corrected according to the discussion in Section 7.1.3.

7.1.2 Control of Nonconforming Items

Documented procedures should be established and maintained in order to ensure that items and materials that do not conform to specifications are prevented from unintended use, installation or release. This control should provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming products, and for notification to the functions concerned.

Identification of nonconforming items by marking, tagging, or other methods should not adversely affect the end use of the item. The identification should be legible and easily recognizable. If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, is then identified.

Nonconforming items should be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions, such as size, weight, or access limitations, other precautions should be employed to preclude inadvertent use of a nonconforming item.

Nonconforming item characteristics are to be reviewed and recommended dispositions of nonconforming items should be proposed and approved in accordance with documented procedures.

Further processing, delivery, installation, or use of a nonconforming item is then controlled pending an evaluation and an approved disposition by authorized personnel.

The responsibility for review and authority for the disposition of nonconforming product should be defined. Personnel performing evaluations to determine a disposition should have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the specifications, and have access to pertinent background information.

Disposition of nonconforming product, and the technical justification for the disposition, should be identified and documented. Nonconformity of an item may be disposed through:

- reworking or retreating to meet the specifications,
- accepting with or without repair or remedy by concession,
- regrading for alternative treatment or applications, or
- rejecting or scrapping.

The description of the nonconformity that has been accepted, and of repair or remedy, is then recorded to denote the actual condition. Repaired, reworked, and/or retreated product should be reinspected, retested, and/or reassessed in accordance with the project-specific quality plan and/or documented procedures.

7.1.3 Corrective and Preventive Action

The participant organization should establish and maintain documented procedures for implementing a corrective and preventive action program. Any corrective or preventive actions taken to eliminate the causes of actual or potential nonconformities are to be appropriate to the magnitude of problems and commensurate with the risks encountered. The responsible organization should implement and record any changes to the documented procedures resulting from corrective and preventive action.

The procedures for corrective action should include:

- effective handling of client, customer or regulatory complaints, and reports of product nonconformities;
- investigation of the cause of nonconformities relating to product, process, and quality system, and recording the results of the investigation;
- determination of corrective action that will eliminate the cause of nonconformities; and
- application of controls to ensure that corrective action is taken and that it is effective.

The procedures for preventive action should include:

- the use of appropriate sources of information, such as processes and work operations that affect product quality, concessions, audit results, quality records, service reports, and customer complaints to detect, analyze, and eliminate potential causes of nonconformities;

- determination of the steps to be taken to deal with any problems requiring prevention action;

- initiation of preventive action and application of controls to ensure that it is effective; and

- confirmation that relevant information on actions taken is submitted for management review.

Refer to U.S. EPA, 2000c for more information on corrective and preventive actions.

7.2 VERIFICATION AND ACCEPTANCE

Verification is confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. Though it is related to the concept of assessment, verification is usually considered an ongoing line management responsibility, rather than as independent oversight.

7.2.1 Verification Tools

Verification involves identifying what goals should be met at various stages of operation or evaluation and whether these goals are still achievable. In some instances, for example, re-evaluation of the process being used or evaluated may merit consideration. Updating of QC specifications during the course of operation, changes in operation or construction activities, or re-evaluation of set standards may be called for if operation does not proceed as planned. If re-evaluation shows that initial QC specifications are not adequate, then the implementation plan should identify a process for ensuring that appropriate changes can be incorporated and that appropriate procedures for approval are followed. Who reviews the process? Who approves changes? How many steps of review are involved? Review processes are included at different stages of design, construction, and operation. These can be conducted prior to initiation of operational start-up and can be conducted subsequently as periodic reviews or after major events, such as operational maintenance.

Verification reviews provide a basic means of assessing the conformance to specifications of any process or operation. Appropriate **technical reviews** conducted within the project ensure that project objectives are being or have been met. The key to conducting successful reviews is to incorporate personnel who have the appropriate expertise to review the portion of the project in question. Qualifications of those being solicited should be assessed by line management before dedicating the resources for the review.

Peer reviews can be similar to technical reviews. They are conducted by someone who was not involved previously in the planning process, but who has suitable qualifications to provide valuable, previously unsolicited, information.

Document/records reviews should be performed to assess whether appropriate and complete records are being maintained. Records to be reviewed should include draft and final reports, plans, procedures, and specifications; technical and peer review comments; steps taken to incorporate comments; technical drawings and specifications; and any inspection or audit reports.

Contract reviews (usually performed during the planning stage) should be performed on draft contracts to ensure that all applicable legal and management requirements are being met. Equally important is determining whether the contract ensures that the contractor will provide a product, process, or service that is consistent with the project quality goals. The contract review should confirm that all appropriate background information has been provided, that the applicable portion of the project scope is clearly defined, that resources are delineated, and that expectations regarding the deliverable or product are provided. In addition, the review should assure that acceptance criteria are detailed in the contract. Contract reviews should also evaluate the impact of any other terms and conditions on project quality. Of primary importance will be the schedule and cost. Has enough time been allotted to allow the contractor to do the job while adhering to quality objectives? Similarly, have adequate resources been allocated to ensure completion of the project using quality materials and qualified labor?

HAZOP review/analysis and other safety reviews are applied in order to confirm that safety procedures are being followed and objectives are being attained. Similar reviews and analyses should be applied for waste disposal operations, environmental emissions, and other areas of regulatory concern. These reviews should confirm that procedures are being followed. Independent of procedural reviews should be analyses of whether the procedures are effectively safeguarding worker, community, and environmental safety.

Management oversight typically involves informal inspections and observation of processes. Project managers may perform such oversight as a way of observing day-to-day activities and ensuring that the system is operating as called for in specified procedures. The observer may not use any formal checklist, but rather may use his/her experience with similar operations and knowledge of operating procedures to identify any obvious problems or failures to operate the system as planned.

Results of the verification review process are recommendations reported to project management, whose responsibility it is to determine if review recommendations should be implemented. Contentious issues may be discussed with all personnel, but ultimate responsibility to make organizational or project improvements resides with project management.

7.2.2 Reconciliation of As-Designed and As-Constructed Projects

In constructed projects, deviations may develop between the contract documents and the as-constructed project. Such deviations are a consequence of field conditions that are different from those envisioned during design or construction problems whose resolution results in a contract change. Reconciliation of as-designed and as-constructed data may involve the development and implementation of a procedure to determine compliance with design documents by the material supplier, fabricator, erector, constructor, etc., and the review and approval of any necessary changes.

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APPENDIX A

TERMS AND DEFINITIONS

activity - an all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.

assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.

audit (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

auditee - the organization being audited.

auditor - a person qualified to perform audits.

authenticate - the act of establishing an item as genuine, valid, or authoritative.

calibration - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.

confidentiality procedure - a procedure used to protect confidential business information (including proprietary data and personnel records) from unauthorized access.

configuration - the functional, physical, and procedural characteristics of an item, experiment, or document.

conformity - an affirmative indication or judgement that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements.

consensus standard - a standard established by a group representing a cross section of a particular industry or trade, or a part thereof.

contractor - any organization or individual that contracts to furnish services or items or perform work.

corrective action - measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

client - any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations. See also Participant and User.

deficiency - an unauthorized deviation from acceptable procedures or practices, or a defect in an item.

demonstrated capability - the capability to meet procurement technical and quality specifications through evidence presented by the supplier to substantiate its claims and in a manner defined by the customer.

design - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

design change - any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

design review - a documented evaluation by a team, including personnel such as the responsible designers, the client for the work or product being designed, and a QA representative, but other than the original designers, to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

document - any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

entity - that which can be individually described and considered, such as a process, product, item, organization, or combination thereof.

environmental data - any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

environmental data operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

environmental programs - activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; laboratory operations on environmental samples; and the design, construction, and operation of environmental technologies.

evidentiary records - records identified as part of litigation and subject to restricted access, custody, use, and disposal.

expedited change - an abbreviated method of revising a document at the work location where the document is used when the normal change process would cause unnecessary or intolerable delay in the work.

extramural agreement - a legal agreement between EPA and an organization outside EPA for items or services to be provided. Such agreements include contracts, work assignments, delivery orders, cooperative agreements, research grants, state and local grants, and EPA-funded interagency agreements.

financial assistance - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and government interagency agreements.

finding - an assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative, and is normally accompanied by specific examples of the observed condition.

grade - the category or rank given to entities having the same functional use but different requirements for quality.

graded approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

guideline - a suggested practice that is non-mandatory in programs intended to comply with a standard.

independent assessment - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

inspection - examination or measurement of an item or activity to verify conformance to specific requirements.

item - an all-inclusive term used in place of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data.

management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

management system - a structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

may - denotes permission but not a requirement.

measurement and testing equipment - tools, gauges, instruments, sampling devices or systems used to calibrate, measure, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

method - a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

must - denotes a requirement that has to be met.

nonconformity - a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.

objective evidence - any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

observation - an assessment conclusion that identifies a condition (either positive or negative) which does not represent a significant impact on an item or activity. An observation may identify a condition which does not yet cause a degradation of quality.

organization - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

organization structure - the responsibilities, authorities, and relationships, arranged in a pattern, through which an organization performs its functions.

participant - when used in the context of environmental programs, an organization, group, or individual that takes part in the planning and design process and provides special knowledge or skills to enable the planning and design process to meet its objective.

peer review - a documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. The peer review is conducted by qualified individuals (or organization) who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. The peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

performance evaluation - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

pollution prevention (P2) - an organized, comprehensive effort to systematically reduce or eliminate pollutants or contaminants prior to their generation or their release or discharge to the environment.

procedure - a specified way to perform an activity.

process - a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

project - an organized set of activities within a program.

qualified services - an indication that suppliers providing services have been evaluated and determined to meet the technical and quality requirements of the client as provided by approved procurement documents and demonstrated by the supplier to the client's satisfaction.

quality - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

quality assurance - an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

quality assurance manager - the individual designated as the principal manager within the organization having management oversight and responsibilities for planning, coordinating, and assessing the effectiveness of the quality system for the organization.

quality assurance project plan - a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

quality control - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

quality improvement - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

quality indicators - measurable attributes of the attainment of the necessary quality for a particular environmental decision. Indicators of quality include precision, bias, completeness, representativeness, reproducibility, comparability, and statistical confidence.

quality management - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

quality management plan - a formal document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

quality system - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

readiness review - a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

record (quality) - a document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media.

reproducibility - the precision, usually expressed as variance, that measures the variability among the results of measurements of the same sample at different laboratories.

research development/demonstration - systematic use of the knowledge and understanding gained from research and directed toward the production of useful materials, devices, systems, or methods, including prototypes and processes.

self-assessment - assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

service - the result generated by activities at the interface between the supplier and the customer, and by supplier internal activities to meet customer needs. Such activities in environmental programs include design, inspection, laboratory and /or field analysis, repair, and installation.

shall - denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.

should - denotes a guideline or recommendation whenever noncompliance with the specification is permissible.

significant condition - any state, status, incident, or situation of an environmental process or condition, or environmental technology in which the work being performed will be adversely affected sufficiently to require corrective action to satisfy quality objectives or specifications and safety requirements.

specification - a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.

source reduction - any practice that reduces the quantity of hazardous substances, contaminants, or pollutants.

standard operating procedure - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

surveillance (quality) - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

technical review - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

technical systems audit - a thorough, systematic, onsite, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

traceability - the ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials.

user - when used in the context of environmental programs, an organization, group, or individual that utilizes the results or products from environmental programs. A user may also be the client for whom the results or products were collected or created.

validation - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.

verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, validation concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

work - the process of performing a defined task or activity (e.g., research and development, field sampling, analytical operations, equipment fabrication).